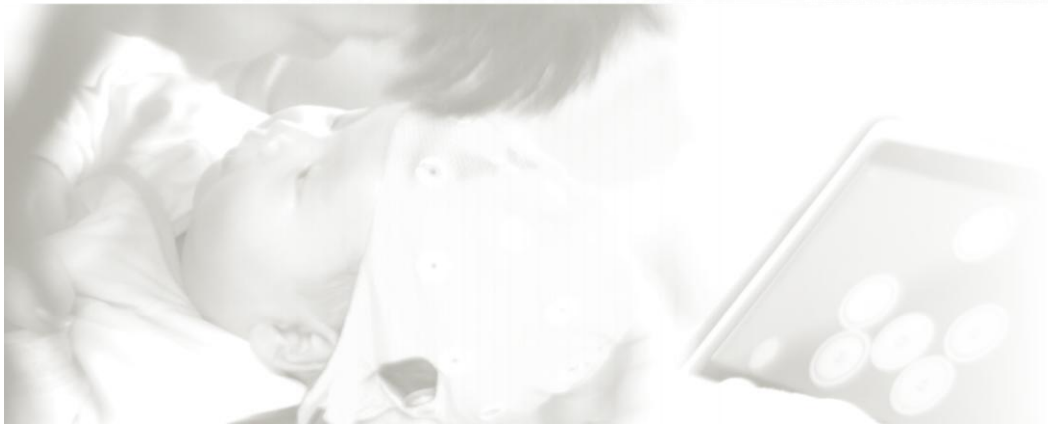
User Manual

nëo monitor system version 1.5, Product code ES-820
including
nëo monitor software version 1.5, Product code: LE-800

User Manual revision 18, March 22, 2026



MANUFACTURER

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REPRESENTATION

The **nëo** products are sold under the **ANT Neuro** brand name; both names are owned by ANT Neuro.
E-mail: support@ant-neuro.com
Website: www.ant-neuro.com

IMPORTANT NOTICES

CE 0044

nëo™ monitor is CE marked as a medical device in the EU, according to MDR 2017/745, CE class IIa, and has received FDA 510(k) clearance in the USA. waveguard™ caps are CE marked as medical device in the EU, according to MDR 2017/745, CE class I, and have received FDA 510(k) clearance in the USA. Manufactured by eemagine Medical Imaging Solutions GmbH, Berlin, Germany, ISO 13485 certified. ANT Neuro and eemagine are part of the neuromotion group.

For US customers:
Rx only
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Note: the automatic annotation of seizure events may not be available in all countries.

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DISCLAIMER

This document is written as accurately as possible. However, mistakes are bound to occur, and we reserve the right to make changes to the products, which may render parts of this document invalid.

MANUFACTURER AND UDI INFO

The manufacturer's information such as name and address can be found in "About" dialog on the software under title "Manufacturer" The About dialog displays the product version along with its Unique Device Identification (UDI) under title "nëo monitor" Figure 1 below provides an example of how the UDI information is presented.

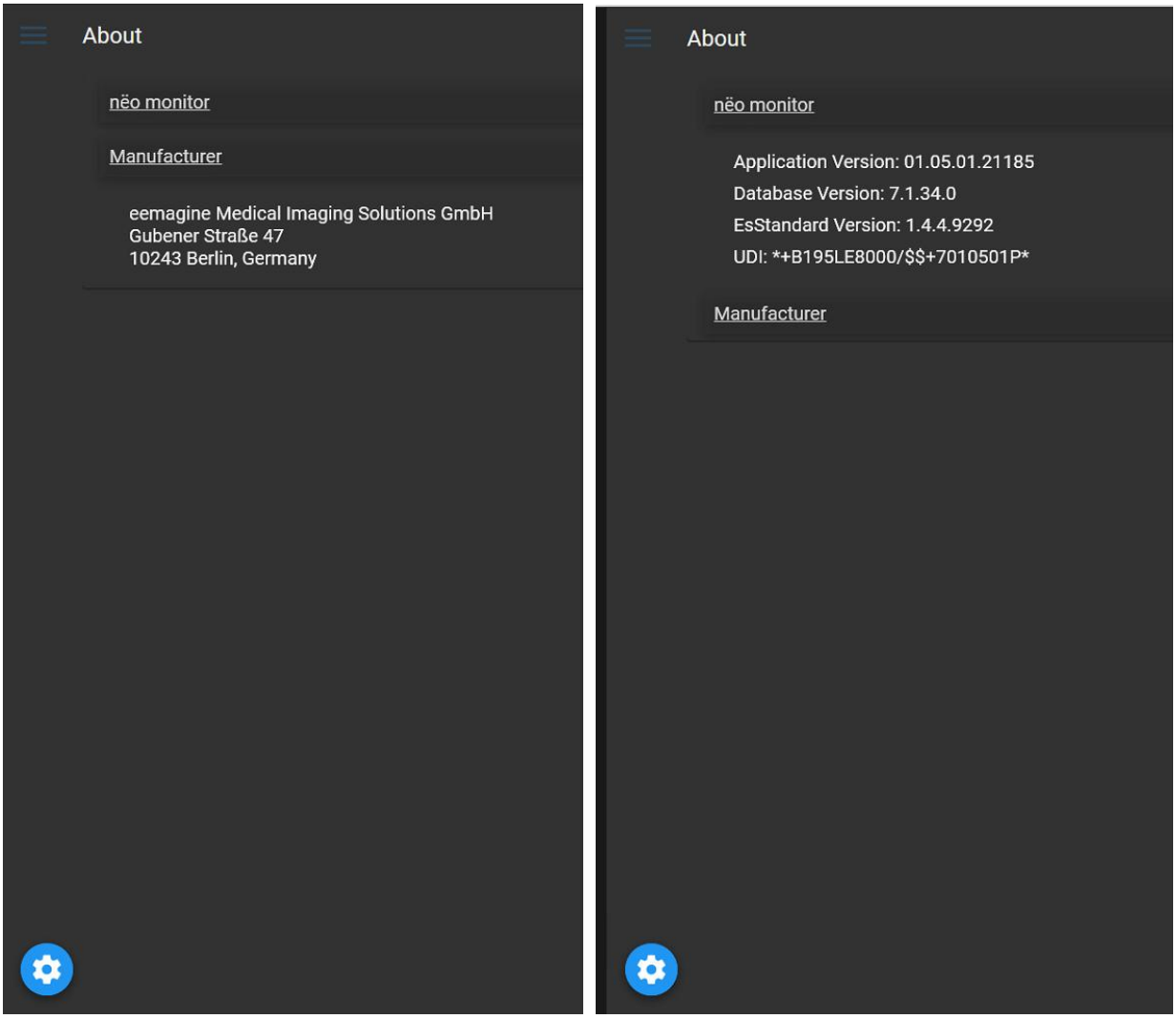


Figure 1 About Dialogue box containing Manufacturer's and UDI info

CONTENTS

1. GENERAL INFORMATION

1.1. About this document

This document serves as the User Manual for **n**ëo monitor software, and the **n**ëo monitor system, which consists of the software, selected components and accessories as required to operate the system. Please note this software and system are intended to be used by experienced neonatal clinical staff only. This manual assumes that the user has basic knowledge of EEG/aEEG recording and has had prior training in using our device. Additional training materials are available on academy.ant-neuro.com.

You must be trained on the basic usage of the device and for the tasks that you perform!
Please inquire with your local representative or the manufacturer on the options to receive training.

1.2. Intended purpose

The **n**ëo monitor is used for electroencephalography (EEG) acquisition and review, intended to record and display EEG and aEEG signals for monitoring the brain status of neonatal patients (defined as from birth to 28 days post-delivery and corresponding to a post-conceptual age of 24 to 46 weeks). The software and system on which it is installed is to be used in a hospital environment by qualified clinical practitioners. The **n**ëo monitor provides neurophysiological data to healthcare professionals to support neurological screening, monitoring and diagnostic workflows.

1.2.1. Indications for use

nëo monitor is indicated for use on healthy and (critically) ill neonates to record and review the cerebral activity of newborn infants, to monitor patients for:

- brain state and development,
- sleep-wake cycles,
- abnormal background patterns (burst suppression, flat trace, etc.),

and for monitoring / diagnosis of patients:

- with hypoxic-ischemic encephalopathy (HIE),
- with clinical seizures (or suspicion thereof),
- for whom there is indication for hypothermia therapy,
- at high risk of brain injury.

The seizure detection algorithm "**SzAssist**" is intended to mark sections of EEG and aEEG that may correspond to electrographic seizures in neonates (defined as from birth to 28 days post-delivery, and corresponding to a post conceptual age of 24 to 46 weeks). The output of the algorithm is intended to assist in post hoc assessment of EEG/aEEG traces by qualified clinical practitioners, who will exercise professional judgment in using the information. The nëo Monitor does not provide any diagnostic conclusion about the patient's condition. (**Note**: The seizure detection algorithm "**SzAssist**" is denoted by symbol "**Sz**" in the software's user interface).

1.2.2. Contra-indications

Contraindications for the use of the **n**ëo monitor system for recording are related to the patient's health and general condition of their scalp or skin. Do not use the system on patients that have/are:

- open wound(s) on the scalp or skin problem,
- not able to tolerate preparation procedures,
- not able to tolerate EEG cap/electrodes.

1.2.3. Clinical claims

The **n**ëo monitor enables:

- evaluation, continuous monitoring and potentially early diagnosis of brain injury or neuropathy which can play a role in preventing neurological impairment.
- early detection and diagnosis of neonatal seizures: the combination of EEG/aEEG can detect seizures in newborns earlier than traditional EEG, which can be critical for timely intervention and treatment.

1.2.4. Clinical benefits

In general, the EEG/aEEG as visualized by **n**ëo monitor provides information to the clinical practitioners on the brain state of the patient, and thereby helps in diagnosing the development or effect of the treatment.

Intended/expected clinical benefit:

- Amplitude-integrated electroencephalography (aEEG) represents a non-invasive, bedside, and simplified method of continuous brain monitoring, mainly assessed by the neonatologist, which has been increasingly used in the NICU in order to access brain function.
- Assessment of brain function in critically ill newborns: aEEG can provide valuable information about the overall status and development of a newborn's brain function, even when they are too young or ill to undergo traditional EEG.
- Monitoring for changes in brain function: aEEG can be used to monitor a newborn's brain function over time to detect any changes that may indicate a developing problem.
- Previous findings have shown that aEEG, as well as the conventional EEG, is a valuable tool to assess background activity, cyclicity, which can be represented by periodical changes in the pattern of aEEG neonatal recording, often referred to as sleep-wake cycling (SWC), and to detect seizures in critically ill neonates as a continuous bedside monitoring.

Specific examples of how aEEG can be used to benefit newborns:

- A newborn is admitted to the neonatal intensive care unit (NICU) with a history of low Apgar scores and seizures. aEEG can be used to monitor the newborn's brain function and identify any seizures that may occur. This information can help doctors determine the best course of treatment for the newborn.
- A newborn is born prematurely and is experiencing respiratory distress. aEEG can be used to monitor the newborn's brain function and assess the impact of the respiratory distress on

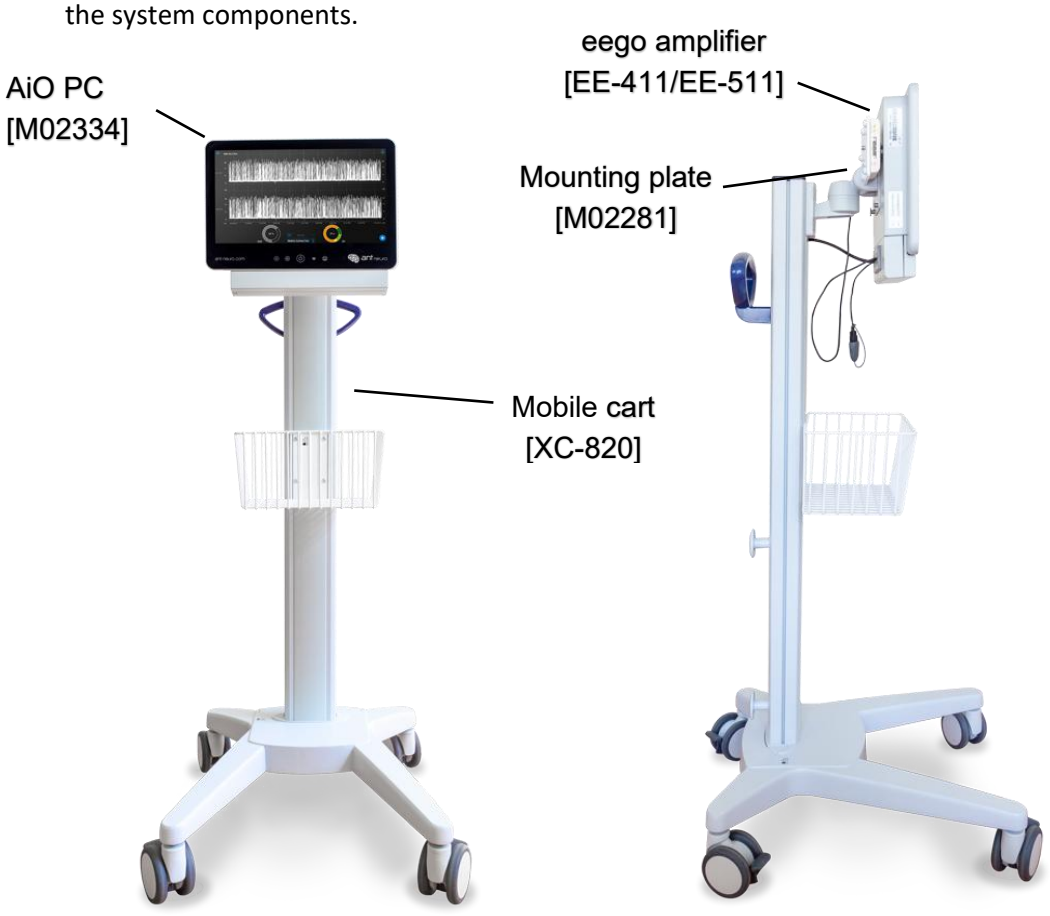
their brain. This information can help doctors determine the best course of treatment for the newborn's respiratory problems and their overall care.

- A newborn is suspected of having hypoxic-ischemic encephalopathy (HIE), a serious brain injury caused by lack of oxygen or blood flow to the brain. aEEG can be used to monitor the newborn's brain function and assess the severity of their HIE. This information can help doctors make decisions about treatment and prognosis.

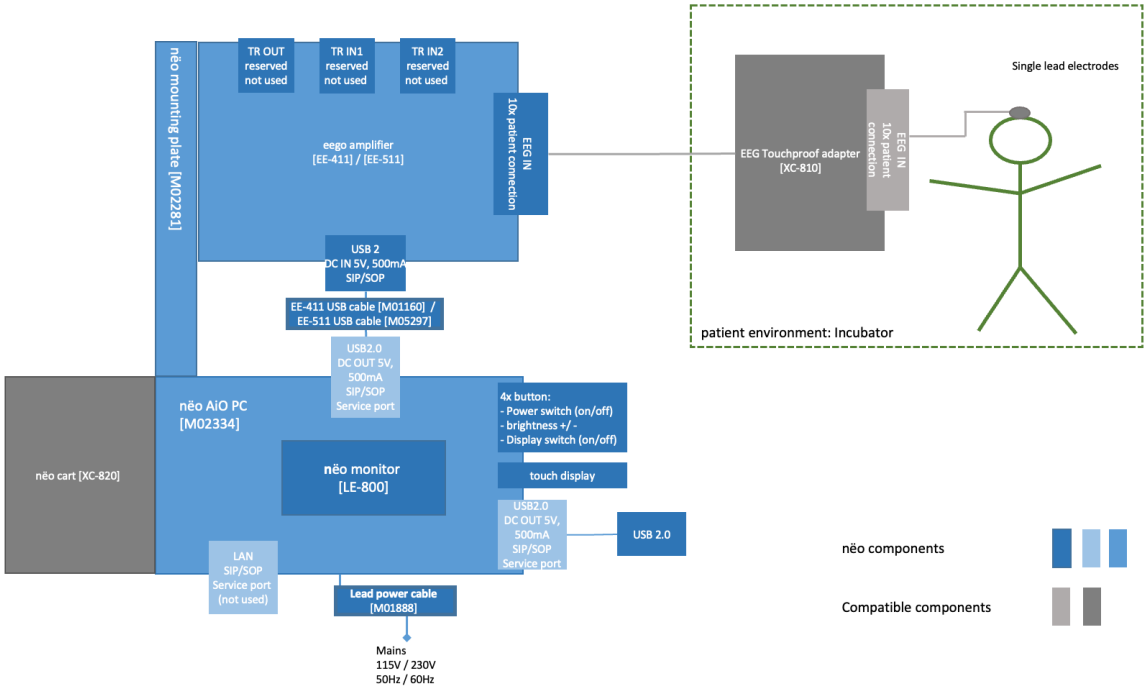
1.3. System components overview

1.3.1. Visual overview

The configuration of the **nëo monitor system** is shown below. Please see section 1.4 below for details on the system components.



1.3.2. Schematic overview



1.4. Compatible accessories with the nëo monitor software

The **n**ëo monitor software operates on a medical panel PC with a USB connection to the **eego** amplifier. The software can be used in combination with compatible types of EEG electrodes, and a touchproof adapter for connecting the electrodes to the amplifier. Accessories to be used in combination with **n**ëo monitor software must meet the requirements listed in Table below. The setup as a whole must meet local medical safety regulations.

Compatible accessories	Requirements
All-in-One PC	• Compliant with IEC 60950, the EMC Directive 2014/30/EC, the Low Voltage Directive 2014/35/EU, the RoHS Directive 2011/65/EU, the Ecodesign Directive 2009/125/EC, and the Radio Equipment Directive 2014/53/EU where applicable. • Multi-touch capable touch screen with: a. minimum resolution: 105dpi (dots per inch) b. minimum display size (pixel): 1200 x 800 c. minimum display size (dimension): 200mm x 150mm • 2 USB-A ports a. USB 2.x or USB 3.x b. Minimum data transfer rate: 480 Mbit/s (High Speed) • x64 processor Intel Core i5/i7 or equivalent • 2GB RAM working memory • MS Windows 10/11 Professional or Enterprise, x64 (English) • Compliance with IEC 60601-1 (depending on local regulation)

EEG amplifier	**eego** amplifier EE-411 **eego** amplifier EE-511 These amplifiers are CE class IIa, part of the eego amplifier product family, manufactured by eemagine Medical Imaging Solutions GmbH
EEG adapters	EEG touchproof adapter XC-810.68 and XC-810.50 Adapter XC-425 (for use with EE-511, XC-810.50 adapter and CA-4xx caps) These adapters are CE class I, part of the waveguard product family, manufactured by eemagine Medical Imaging Solutions GmbH
EEG electrodes	The system should only be used with market-cleared electrodes. Users should read and follow the manufacturer's instructions for the specific electrodes that are used. • CE marked for clinical use with neonatal patients • Gold cup electrodes, Ag/AgCl electrodes, hydrogel sticker-electrodes or subcutaneous steel needle electrodes • Cable length between 30 cm to 150 cm • Compatible with 1.5mm touchproof connector
EEG caps	**wave**guard original cap CA-4xx & CA-5xx (eemagine Medical Imaging Solutions GmbH) • Compatible with **eego** amplifier EE-411 or EE-511 • Sizes N1, N2, N3, N4, N5, B, I, C • CE marked for clinical use with neonatal patients These caps are CE class I, part of the waveguard product family, manufactured by eemagine Medical Imaging Solutions GmbH
Mobile cart	Mobile cart [XC-820] Compliant with applicable sections of IEC 60601-1:2005/A1:2012. This cart is CE class I, manufactured by ITD GmbH
Mounting plate	Mounting plate [M02281]. Plastic plate to hold the eego amplifier securely in place. Manufactured by eemagine Medical Imaging Solutions GmbH

1.5. Safety warnings

The following warnings and cautions apply to **n**ëo monitor system and **n**ëo monitor software:

- **n**ëo monitor system and software must only be used by trained personnel.
- In cases of ambiguous data potentially informing clinical decisions, both the aEEG and EEG need to be evaluated by trained personnel with expertise.
- Compatible accessories used in combination with the **n**ëo monitor system and software may have their own additional warnings and cautions as listed in respective user manuals. Make sure to read and comply with them.
- Non-compliance with warnings and safety regulations may result in severe personal injury to the patient and/or the operator!
- Note that aEEG is known to be subject to common NICU artifacts (e.g. ECG, muscle activity, and high-frequency ventilation) and therefore should always be interpreted with caution and in combination with simultaneously recorded raw EEG signal.
- Ensure that the data are sufficiently free of NICU artifacts by reviewing the EEG quality at the start of the recording, at regular intervals, and whenever the technical environment changes. Failure to do so may result in missing important information during monitoring and subsequent harm of the patient.
- The **n**ëo monitor software checks for technical abnormalities at regular intervals and displays a warning message in case of high impedance, possible excess of the amplifier's measurement

range, loss of data connection or PC problems. Make sure to check for those warning messages at regular intervals and to attend to the system in case of a warning. Failure to do so may result in missing important information during monitoring and subsequent harm to the patient.

- **n**ëo monitor software is not designed to monitor vital processes where variations could result in immediate danger. Other means of vital signs monitoring must be used.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of your country.

1.5.1. Safety measures

- Do not use **n**ëo monitor system with devices not explicitly listed to be compatible.
- Use **n**ëo monitor system only with compatible electrodes or caps.
- Do not store or operate the system outside the specified environmental conditions for temperature, humidity and air pressure as specified in the datasheet.
- The only power cord that may be used is the original power cord supplied together with the PC. DO NOT replace it with anything else. If any third-party power cord is used then patient safety is not guaranteed.
- Make sure that the wall socket is well earth grounded and complies with standard installation rules.
- Inspect the power cord of the PC on a regular basis for damages. Do not operate the device with a damaged power cord.
- Do not connect active sensors or electrodes to any of the inputs of the amplifier.
- Take care when arranging patient and electrode cables to avoid risks of entanglement or strangulation. Do not pull on the cables when they are connected to the patient.
- Secure the EEG adapter for the electrodes at the incubator. Use the opening for the strap to ensure strain relief if necessary.
- If you operate the system on a medical cart, make sure always to secure the wheels with brakes to avoid an accidental movement of the system and a pull on the electrode cables.
- Reusable electrodes present a potential risk of cross-contamination. Please refer to the documentation that came with your electrodes for instructions on how to prevent this.
- An improperly cleaned breakout adapter presents a potential risk of cross-contamination. Please refer to the documentation that came with the adapter on how to prevent this.
- Do not connect the software and compatible accessories to a patient undergoing MRI, electro-surgery or defibrillation.
- Do not combine **n**ëo monitor system with other devices without carrying out your own detailed risk analysis involving experts in the field.
- WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- ELECTRICAL SHOCK HAZARD: Do not connect electrode inputs to earth ground. Connecting an earth ground might result in electrocution.
- Conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL/GROUND/REFERENCE ELECTRODE, should not contact other conductive parts including earth.

- The **n**ëo monitor system is not for installation by the customer including IT personnel! It is always to be installed by trained support personnel or distribution representatives of the manufacturer. An integration test with the amplifier and all auxiliary parts is always required during the installation procedure.

1.5.2. Precautionary measures

- The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in APPENDIX B: NËO MONITOR TECHNICAL SPECIFICATIONS (EMC); the use of accessories other than specified may result in increased emissions or decreased immunity of the system and result in improper operation.
- The performance of the **n**ëo monitor system was determined to be according to the descriptions in APPENDIX A: ESSENTIAL PARAMETERS. The user can expect distorted signals that are clearly different from EEG signals if degraded due to electromagnetic disturbances.
- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the nëo monitor system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Disposable electrodes that are used for electrophysiological measurements may pose a biohazard. Handle, and when applicable, dispose of these materials in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.

1.5.3. Additional safety warnings

- The **n**ëo monitor system and its components are not suitable for use in an environment with an inflammable mixture of anesthetics and air, oxygen, or nitrous oxide.
- The **n**ëo monitor system and its components are to be kept dry. Clean the all-in-one PC and adapter only with non-aggressive solution suitable for screen cleaning and silicone disinfection as described in this manual.
- Do not apply heavy pressure on the adapter when connecting or disconnecting electrodes. Mishandling the adapter can lead to equipment damage.
- Check regularly whether the skin of the patient is irritated by electrode pressure or gel contact.
- When using needle electrodes with the **n**ëo monitor system, a filter artefact in the signal may occur directly following the automatic impedance check due to a known and expected capacitive effect in needle electrodes.
- If any liquids or moisture penetrate hardware components used with the **n**ëo monitor system, turn the device off, remove the plug from the wall socket and have the device checked by the manufacturer.

- Do not expose the **n**ëo monitor system and its components to direct sunlight, heat from a source of thermal radiation, excessive amount of dust, moisture, vibration, or mechanical shock.
- Do not wind the cables in loops smaller than 5 cm or bend them sharply, as this may damage the cables.
- Do not use the **n**ëo monitor system when any accompanying part is damaged.
- The **n**ëo monitor system is not defibrillator-proof.
- You may not install additional programs on the PC as this may compromise performance when recording and reviewing data or cause software conflicts.
- Make sure to comply fully with your local cybersecurity guidelines. Please take care of data anonymization or encryption if needed.

1.6. Maintenance

The **n**ëo monitor system requires weekly checks of general cleanliness and sufficient remaining recording time. See section 12 for information on cleaning. The remaining recording time is displayed on the start screen of the **n**ëo monitor software, see section 4.1.

The Microsoft Windows Operating system including Windows Defender and virus definitions, and the Microsoft SQL server software installed on the PC should be updated with latest Microsoft security patches . The Windows Operating system and SQL server software update must be performed by a trained technician and is required every 12 months or more frequently, according to your local regulations. Refer to the **n**ëo Deployment Guide (Section 6. System Maintenance) for instructions on how to perform the update. Failure to service regularly may result in software conflicts, reduced functionality, or system instability. Such issues can negatively affect software performance and may prevent proper operation.

If an update to the **n**ëo monitor software is recommended or required, you will be contacted by your distributor or by ANT Neuro. It is mandatory to apply the Microsoft Windows Operating system and Microsoft SQL server software updates prior to updating or upgrading the **n**ëo monitor software. It is strongly recommended that users perform regular backups and ensure that the hard drive of the **n**ëo monitor system has adequate storage space, see section 8.

1.7. System and data protection

After powering up the system, **n**ëo monitor software will ask for a password to log in. The initial password is “neo” (without quotes). We strongly recommend that a new secure password is set during the deployment of the system at your local institution. Please align with your local IT department for details on PC protection or if you lost the **n**ëo monitor system password. Remember to keep the password safe at all times.

nëo monitor software protects access to patient data by a security password. Patient data is accessible in the Patients and Review workflows. The initial password is set to “0000” (without quotes). To change the password, go to the Technical setup workflow. We strongly recommend that a new secure password is set prior to the start of the system being put into service. Remember to keep the password safe at all times.

nëo monitor software also protects access to the Technical setup by a security password. The initial password is again set to “0000” (without quotes). The password can be changed from within Technical setup workflow. We strongly recommend that a new *secure* password is set prior to the start of the system being put into service. Remember to keep the password safe at all times.

If the Patient data password or the Technical setup password is misplaced or forgotten, please contact support with your installation details and proof of eligibility.

If you connect USB storage media for export and backup of data, make sure to use only devices that are virus and malware controlled. Please align with your local IT department for details. Do not disable the virus protection of the **nëo monitor system** PC!

Do not keep any USB devices connected while monitoring is in progress; however, temporary USB connection is allowed solely for exporting screenshots during monitoring. The USB device must be connected only for the duration required to complete the screenshot export and then promptly removed. Improper or prolonged USB use during monitoring may interfere with data acquisition and compromise recording quality.

For advanced security, the hard drive of the **nëo monitor system** PC is encrypted using Microsoft’s Bitlocker technology. Do not disable Bitlocker encryption!

Please contact your local distributor in case of any security issues, see section 1.8.

1.8. Disposing of waste equipment

Special EU instructions for disposal are applicable to a product on which this symbol is placed. Various parts of the **n**ëo monitor system bear this symbol. This is also applicable to the USB-cable.

The symbol means that the products must not be disposed of with other waste. Instead, it is the user’s responsibility to dispose of their waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service.

Disposal of PC hardware is to be defined by your local regulations.

2. START COMPUTER

Button	Function
	Turn the unit on/off (hold for 2 seconds)
	Brightness control: brighter
	Brightness control: darker
	Turn display and touch screen on/off (hold for 2 seconds)

After the computer is turned on and credentials are successfully proven for the neo Windows user, **n**ëo monitor software will automatically launch.

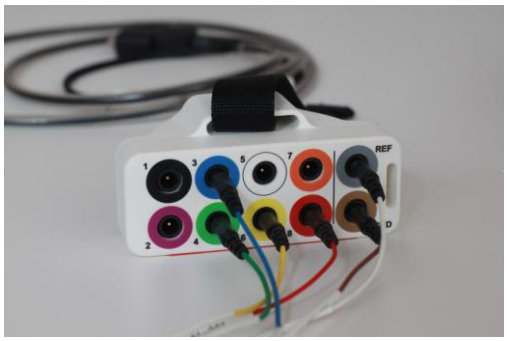
Make sure that the hardware switch on the right flank of the computer is turned on (picture below).

LED	**Status**	**Info**
	On	The unit is operating
	Flashing	The unit is in standby mode
	Off	The unit is not connected to the mains
	On	Accessing mass storage

Hardware switch

3. APPLYING ELECTRODES and CONNECT AMPLIFIER

3.1. Apply electrodes and connect to EEG touchproof adapter



Please refer to the user manual of the electrode manufacturer when applying electrodes on your patient.

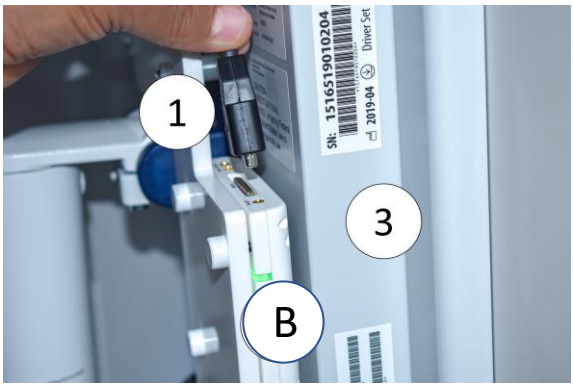
See APPENDIX G: nëo aEEG ELECTRODE POSITION AID INSTRUCTIONS on how to use the electrode position aid.

Plug the electrode touchproof connectors into the according sockets on the EEG touchproof adapter. Do not apply heavy force. It is recommended that colors of the individual electrode cables match the color of the socket; however, it is not required.

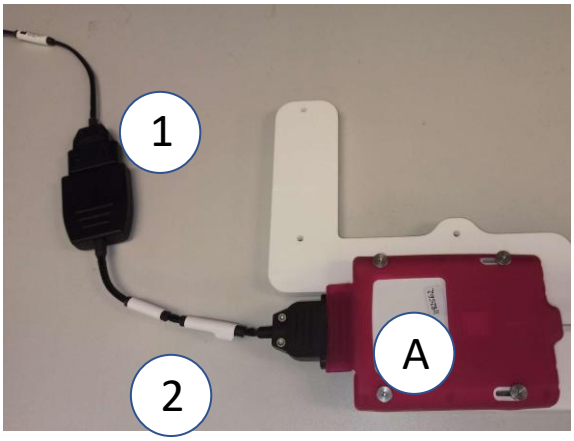
3.2. Connect EEG touchproof adapter or EEG Cap to nëo

Plug the high-density connector of either the EEG touchproof adapter or EEG cap to the compatible socket on the EEG amplifier. There are two amplifier types:

A. Current amplifier is EE-511, which has a rose color soft shell. XC-425 adapter is required for connection to older XC-810.50 EEG touchproof adapter or CA-42x caps. =
B. The previous amplifier is EE-411, which has a white plastic housing.



1. High-density connector of EEG touchproof adapter or EEG cap
2. Adapter XC-425 for amplifier EE-511, EEG touchproof adapter XC-810.50 and CA-42x caps
3. nëo All-in-One PC



The high-density connector is asymmetric which prevents inserting it in the wrong direction. Please do not apply high force when connecting to the amplifier or adapter. The adapter XC-425 is only used with the EE-511 amplifier, as 'go-between' for the older version of the XC-810.50 adapter

/ CA-4xx caps. The XC-425 adapter is not required with the newer CA-5xx caps and current version of XC-810.68 adapter.

4. EEG/aEEG DATA ACQUISITION

4.1. Select a recording protocol

Turn the PC on and log in. The **n**ëo monitor software automatically starts.

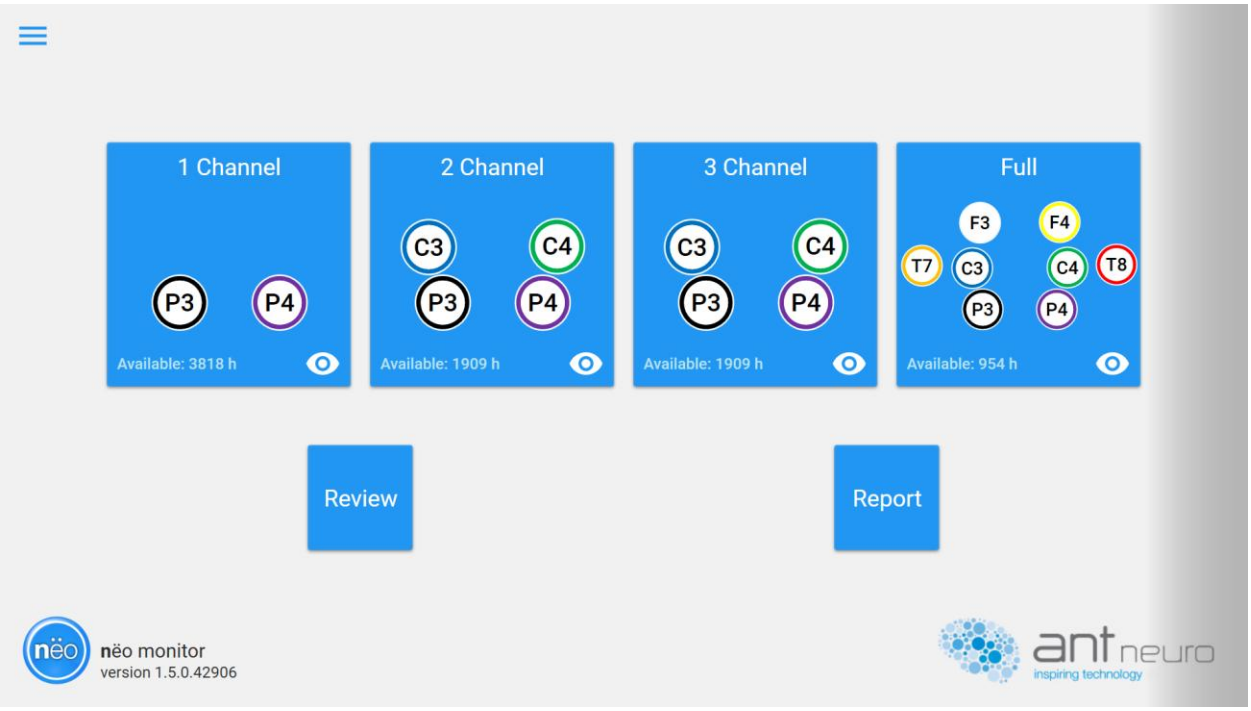


Figure 4-1 Start screen

For devices connected to a Hospital Information System, active orders are displayed in a panel on the right side. This panel can be opened with a single finger swipe to the left or selecting “Orders” in the main menu dropdown. Once an order and protocol are selected, the recording is automatically assigned to the order.

Figure 4-2 Start screen with the orders side panel

Select the suitable monitoring protocol by pressing on the corresponding ***Protocol*** button.

Confirm that the selected protocol matches the electrode setup defined by your institution to ensure that no data is missing.

Assess Information about hardware settings of each protocol (e.g., amplifier type, montage, and sampling rate)

The capacity of remaining hours of recording available on the systems hard drive for the selected protocol is displayed as remaining available recording hours.

4.2. Check impedance values

The *Impedance* screen displays an axial view of the electrode layout. Each electrode is represented by their channel name and impedance value. The color of the ring or border of the circle corresponds to the input of the EEG touchproof adapter The impedance value is reflected by the color of the circle body, where impedances below 30kOhms will be green and impedances above 30kOhms will be red. Start with the GND and REF electrodes. Impedances will only display once the first electrode after GND and REF are applied.

Once impedances are sufficient, start monitoring by selecting the **Signal** button in the lower right corner.

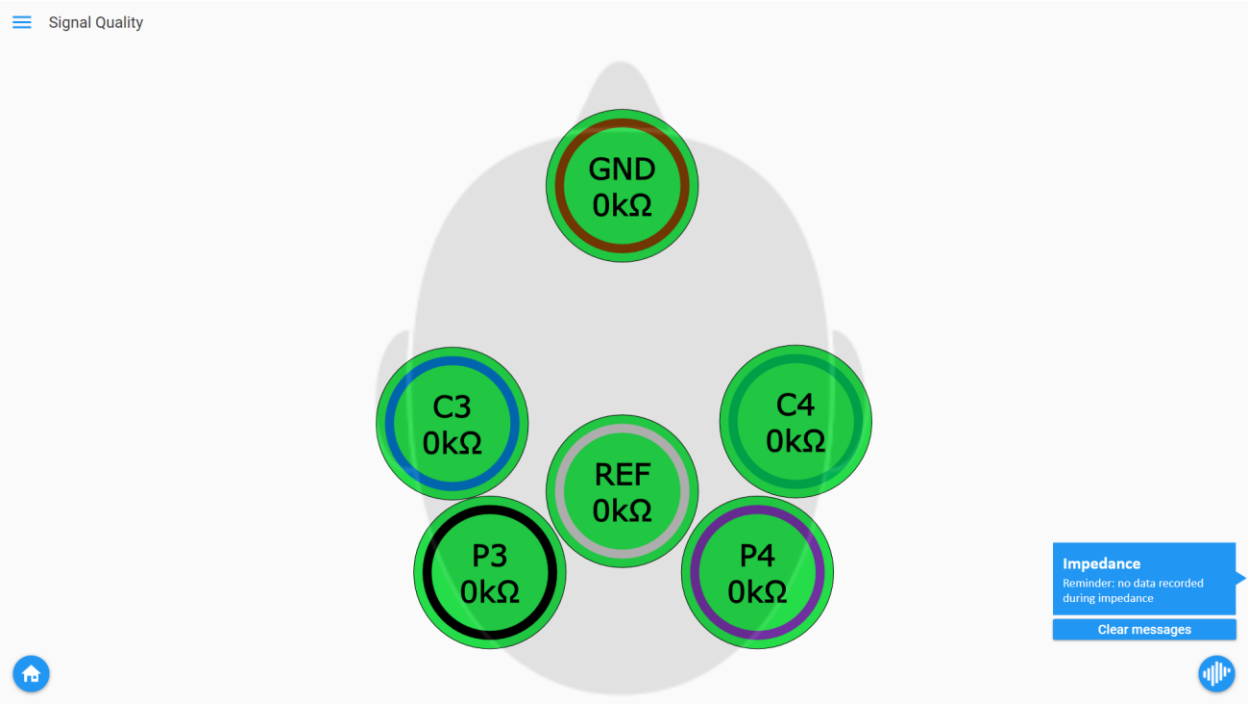


Figure 4-3 Impedance screen for the 2 Channel recording protocol with low impedances

Start monitoring by pressing the **Signal** button on the bottom right corner.

Pressing the **Start screen** button in the bottom left corner will take you back to the start screen.

The head symbol represents the patient's head and direction the patient is facing. The top of the head symbol with the nose indicates the face of the patient.

Please closely follow the respective user manual when applying different types of electrodes.

For older systems with EE-411 amplifier and when using **subcutaneous needle electrodes**, the impedance view shows in binary state whether an electrode is properly inserted.

4.3. Start EEG/aEEG Data Acquisition

By pressing the **Signal** button, you proceed from *Impedance* to *Acquisition* mode, and the recording of EEG/aEEG data starts immediately stating 'Monitoring' in the middle of the screen. Please note that since aEEG is derived from the underlying raw EEG at a regular interval of 15 seconds, no aEEG will be

displayed for the first 15 seconds upon starting the recording. The user interface of the *Acquisition* screen is shown in Figure 4-.

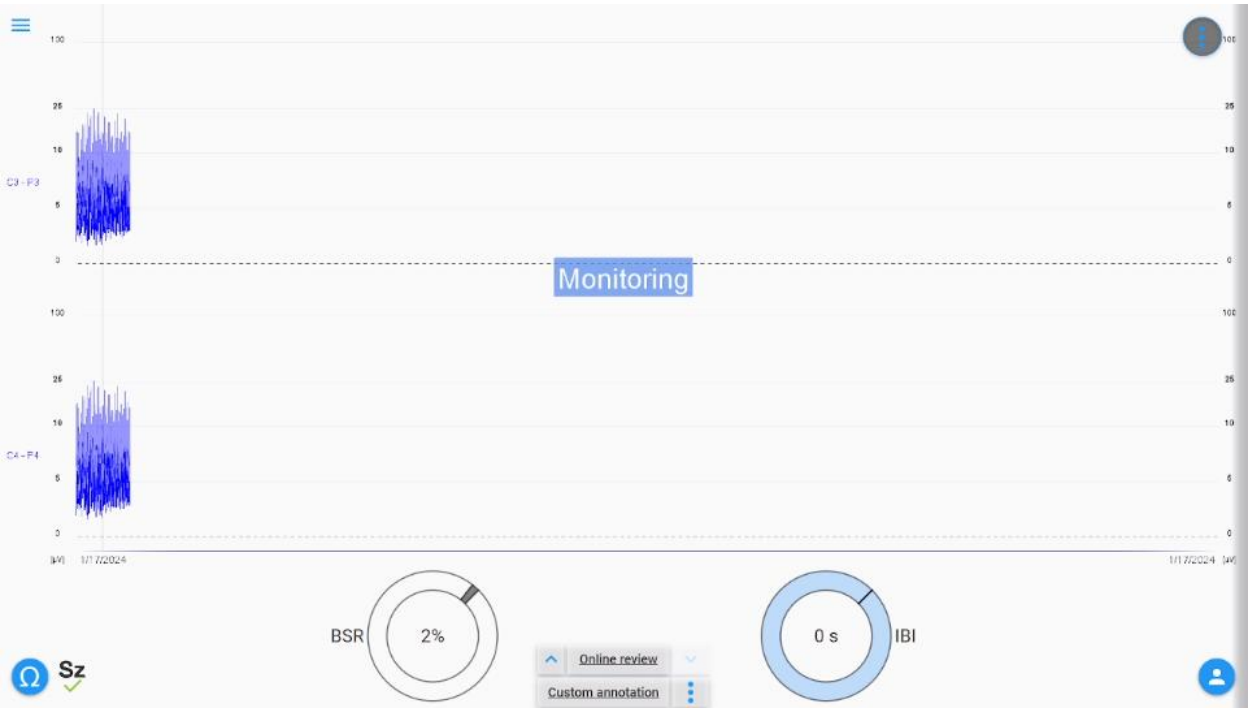


Figure 4-4 User interface of the Acquisition Screen

Pressing the **Patient** button on the bottom right corner will open the patient management menu (refer to Chapter 9). During the patient management view, the EEG/aEEG recording continues in the background. After linking the recording with a patient, the **Patient** button will be replaced by the **Stop** button.

Pressing the **Stop** button in the bottom right corner will end the current monitoring session and exit to the start screen.

Pressing the **Impedance** button will lead back to the impedance screen. After making sure that the impedance values are sufficiently low, you can switch back to the previous data view by pressing the **Signal** button on the bottom right corner. Please note that no data is recorded or computed under *Impedance* mode.

4.4. Bad Signal Quality Warning

For all electrode types, a quality analysis is monitoring the EEG signal for artifacts parallel to the recording. It monitors the powerline hum, drift, and flat EEG lines. If bad signal quality is detected the **n**ëo monitor software notifies the user with a visual warning (refer to chapter 4.9)

Bad signal quality indicates one of the following possible causes:

1) Electrode contact not sufficient
    a. Check Reference (REF) and Ground (GND) electrode contact and one additional EEG electrode
    b. Check the rest of electrode positions
2) A nearby source of electrical noise
    a. Check third-party devices that may emit electrical noise close to the **n**ëo monitor or electrode cables. Electrical devices such as computer, mobile-phones or other medical devices can be the source of electrical noise.

4.5. EEG and aEEG Views

aEEG view

The aEEG view is the default initial acquisition screen and displays the incoming stream of aEEG data. On the bottom screen Inter Burst Interval (IBI) and Burst Suppression Ratio (BSR) are displayed. Channel names are shown at the left of each trace.

By default, the aEEG is displayed in semi-transparent mode called “greyscale”. This mode allows a more refined view on the amplitude distribution of the EEG within the 15 second time period of one aEEG sample. To use the traditional opaque aEEG display instead of greyscale mode, switch the display settings in the Technical setup workflow.

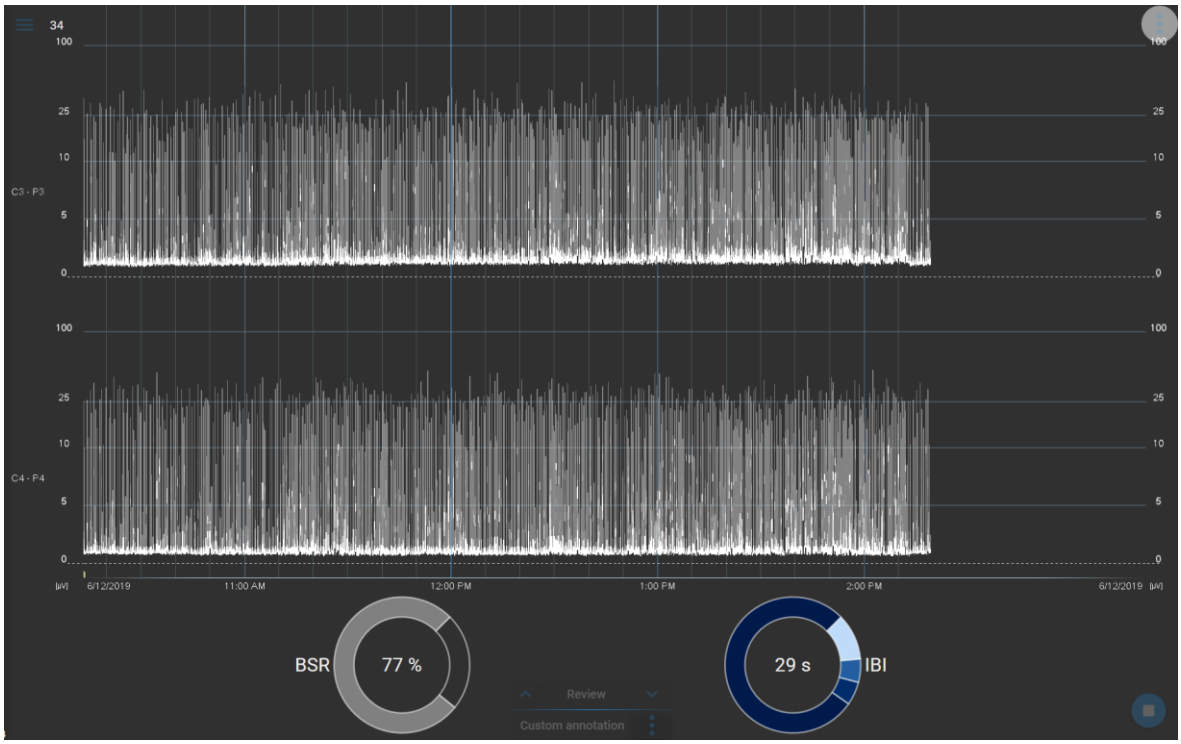


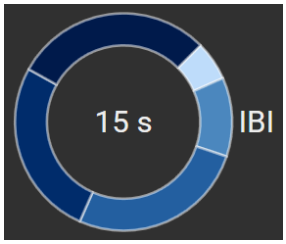
Figure 4-5 aEEG view with visualization of Burst Suppression Ratio (BSR) and Inter Burst Interval (IBI)

Via the Options 3-dots ellipsis button in the upper right corner of the aEEG window, parameters such as timescale or visible channels can be adjusted. Hiding a channel only affects their visibility, the data is recorded in the background.

The default time axis for aEEG is 6 cm/hour (clinical standard). The aEEG amplitude scaling for 0 – 10 µV is linear and is logarithmic from 10 – 100 µV.

The **Burst Suppression Ratio (BSR)** and **Inter Burst Interval (IBI)** are updated every 4 seconds and calculated with the EEG/aEEG recording from the last 10 minutes.

Burst Suppression Ratio (BSR): The BSR is calculated as the percentage of suppression periods. The resulting BSR value is shown in the middle of the circle and indicated by grey shades on the circle. For example, if BSR value for the last 10 minutes is 77%, 77 percent of the circle will be filled with grey color.



Inter Burst Interval (IBI): The average of the IBIs from last 10 minutes is shown in the middle of the circle. In addition, the distribution of all IBIs within these 10 minutes is classified into one of the following categories depending on their length: 2 -5 s, 5 - 10 s, 10 - 20 s, and > 20 s, and displayed in the outer circle.

NB. The background for these technical indicators are further explained in 13.3.

EEG view

The EEG view can be opened any time during the recording with the EEG UP button:

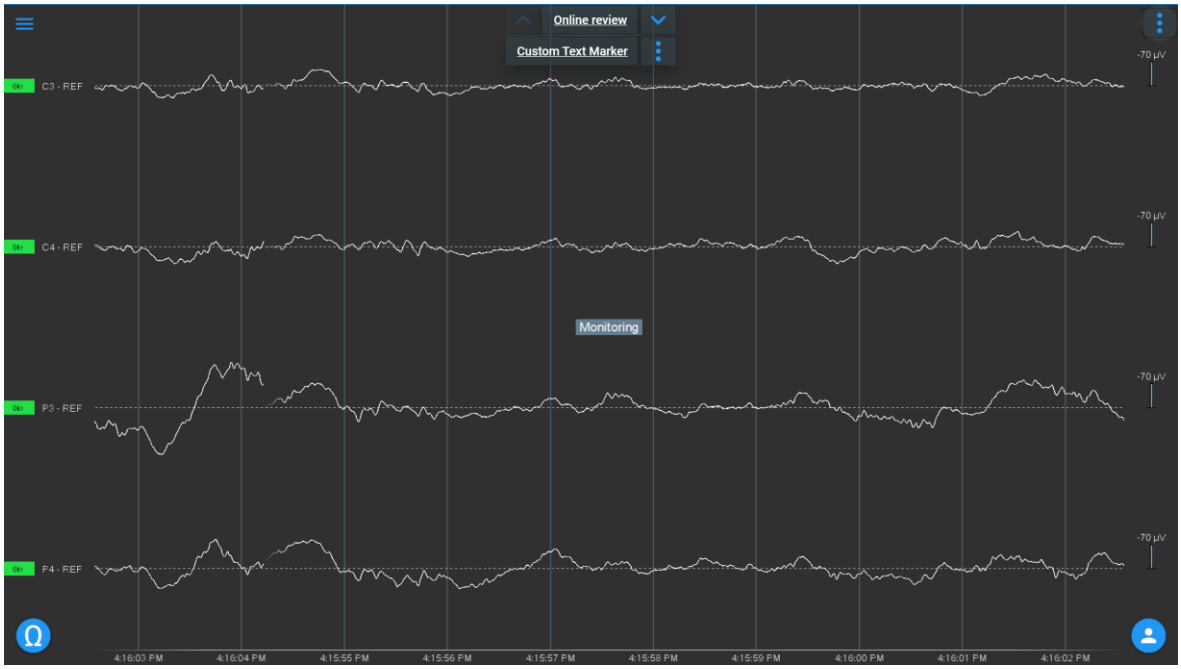
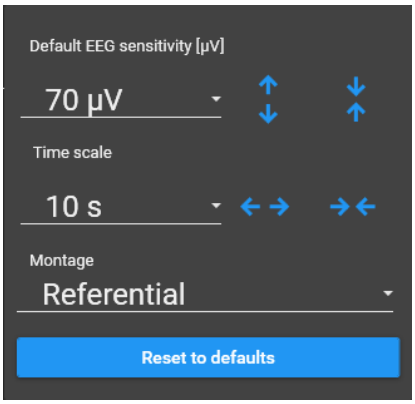


Figure 4-6 EEG view

You can scroll across the EEG channels by panning vertically in the data area and change the spacing of the channels by pinching vertically in the label area.

Via the Options 3-dots ellipsis button in the upper right corner of the EEG window, parameters such as timescale, EEG sensitivity or montage can be adjusted.



The impedance indicator on the left side of each channel shows the most recent impedance value measured for each electrode.

4.6. aEEG/EEG split-screen

The aEEG and EEG view can be combined in a split-screen and can be triggered by either EEG up or EEG down button, depending which view was previously displayed.

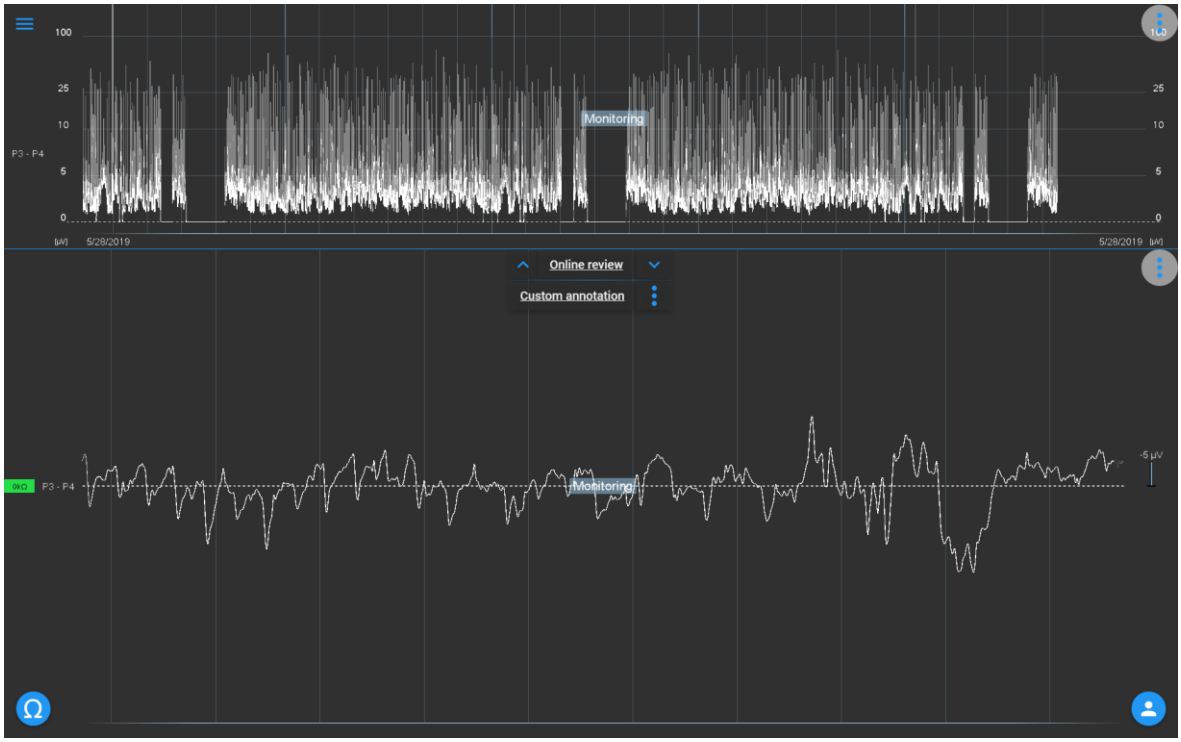


Figure 4-7 EEG and aEEG displayed in a split-screen

4.7. Online review

During a recording, online review is possible at any time.

Figure 4-8 EEG and aEEG displayed in a split-screen during online review

Push the **Online review** button to switch to aEEG and EEG review, while data is recorded in the background. 'Review' will be stated in the middle of the screen. Use the **EEG UP** and **EEG Down** buttons to switch between different data views.

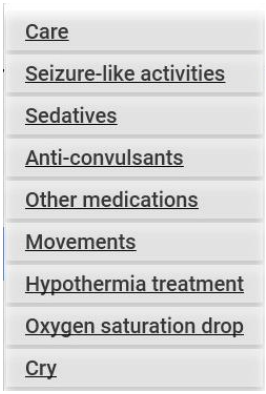
To return to the live acquisition mode, push the **Monitoring** button.

The Online review has the same functionalities as **Offline Review**, please refer to Chapter 5, as of section 5.2. Note: During Online review, EEG/aEEG data is recorded in the background.

4.8. Annotations

During a recording, annotations and markers can be set at any time.

Use the 3-dot ellipsis **Dropdown** button for inserting standard annotations, which by default include the following:



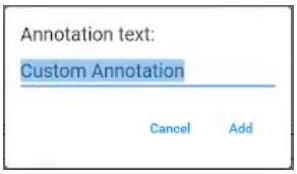
See section 13.8 for the available standard annotations and how to customise in Technical setup.

Standard markers are inserted immediately after the button is pressed.

During online and offline review, activate the EEG cursor by tapping the timepoint of interest in the EEG prior to placing an annotation. Note: If the EEG cursor is not activated, the annotation will not be inserted.

Push the **Custom annotation** button to insert a custom text annotation.

Custom annotations are inserted immediately when the button is pressed, while a window is kept open for inserting the custom text.



4.9. Screenshots

Screenshots can be created the same way an annotation is placed. Press the '3-dot ellipsis' button to the right of 'Custom Annotation' to open a list of available annotations. Select "Report Screenshot' at the top.

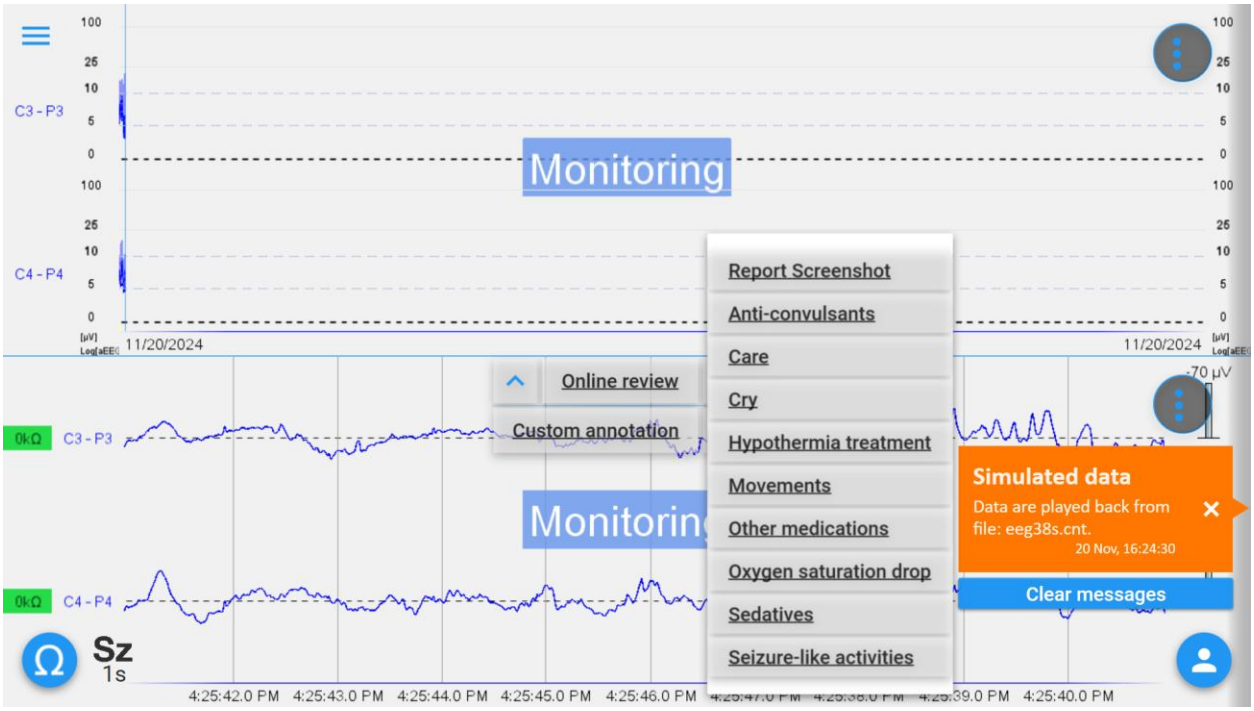


Figure 4-9 Default list of annotations. Note: Simulated data are for demonstration purposes only.

Add a note for the screenshot.

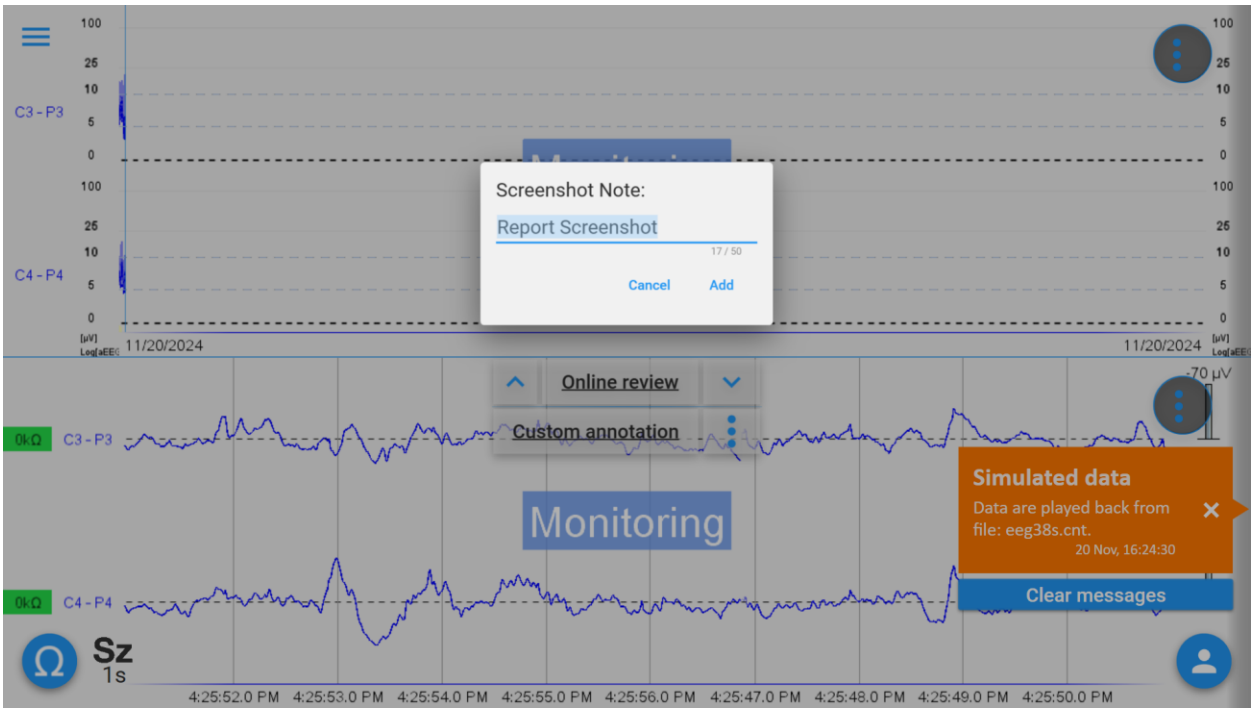


Figure 4-10 Example of custom annotation. Note: Simulated data are for demonstration purposes only.

To view the screenshot, open the Annotation List side panel by either single finger swiping to the left or selecting Annotation List from the main menu dropdown. Select annotation type “Report Screenshot” from the ‘3-dot ellipsis’ button in the top left corner of the panel.

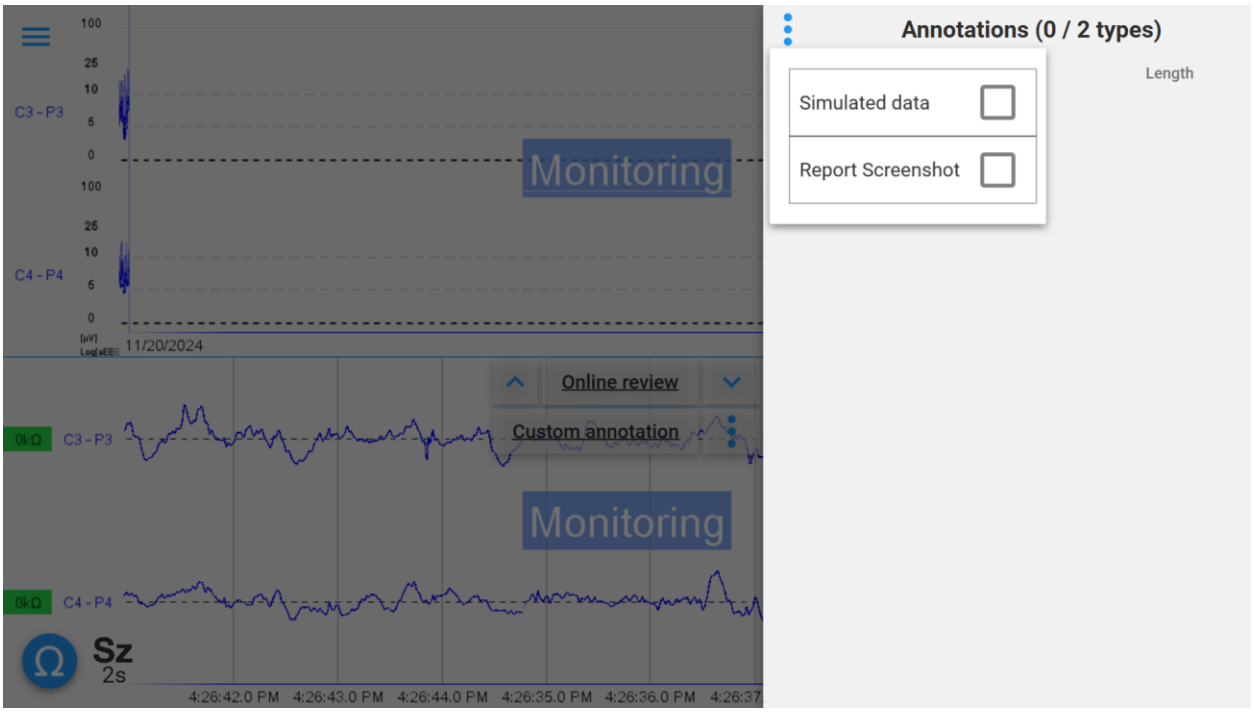


Figure 4-11 Annotation list displaying the annotation types

The screenshot that was just created will be listed. Press on the **Preview** button to view the screenshot and any notes.

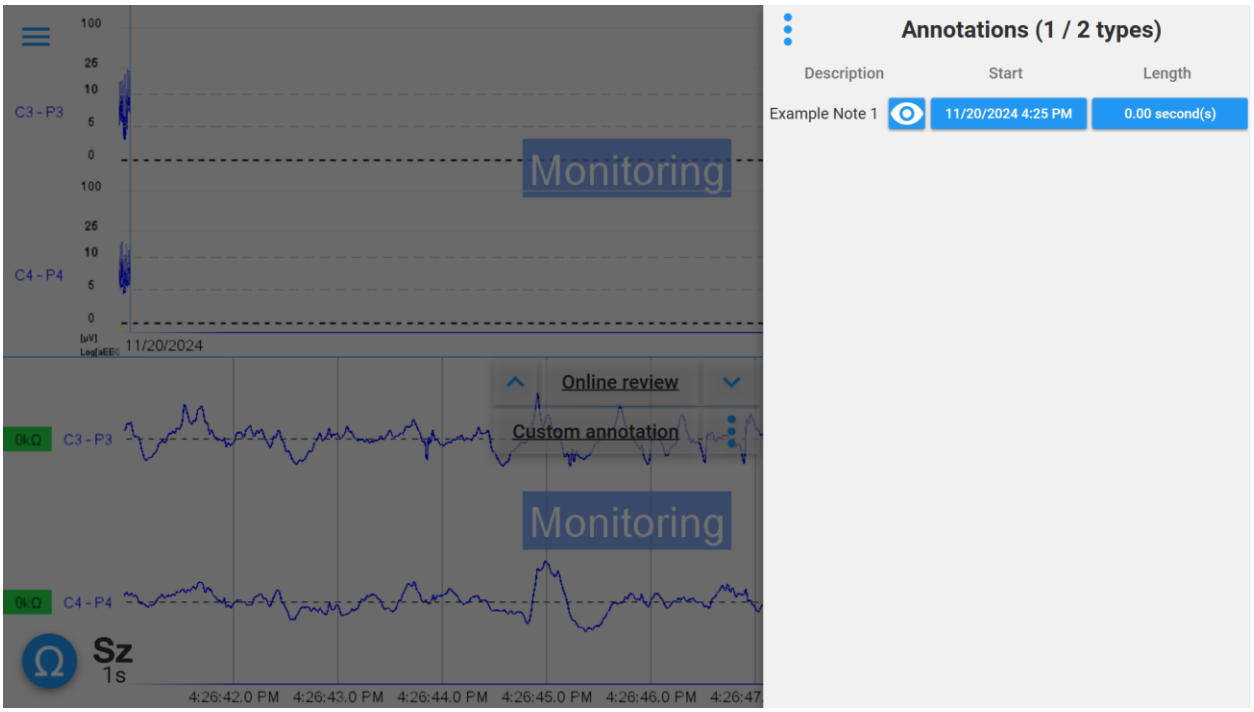


Figure 4-12 Display of a single annotation in the Annotation list

The screenshot will display and a PDF can be exported by selecting **Export**. Screenshots can be added to Reports when creating a report.

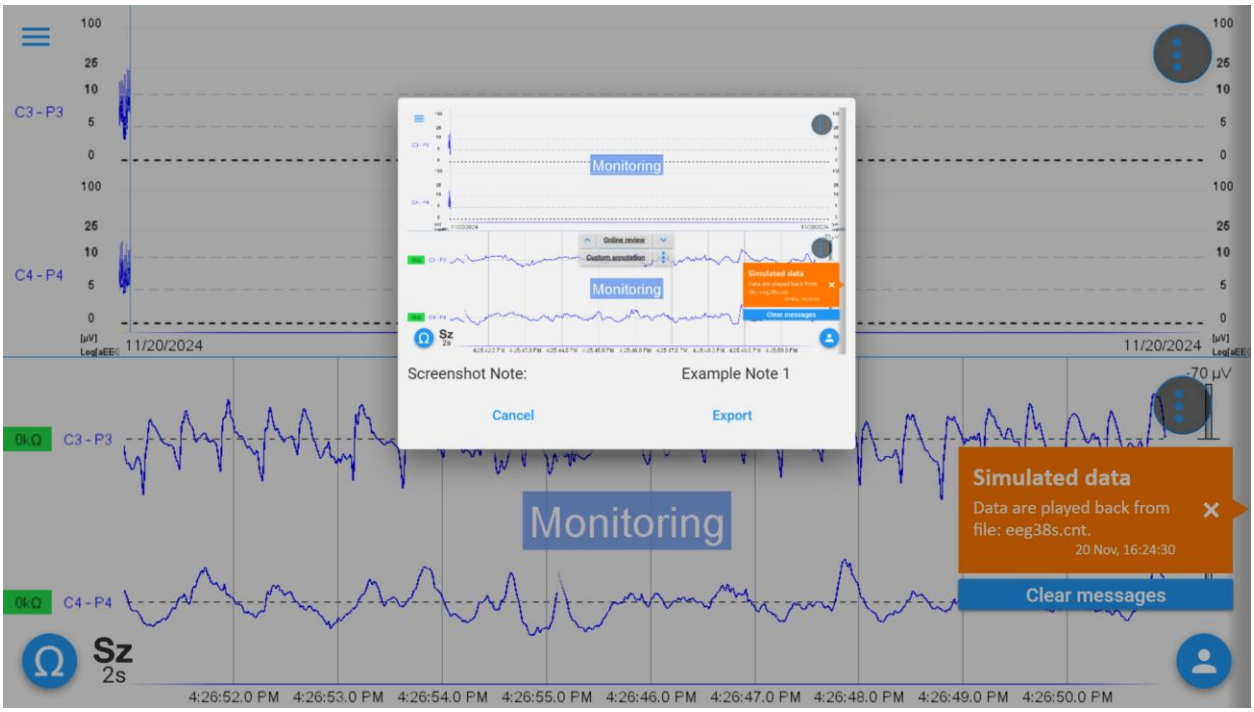
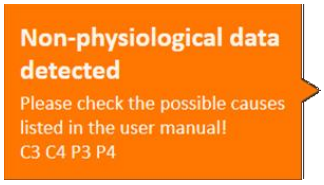


Figure 4-13 Preview of a screenshot with example note. Note: Simulated data are for demonstration purposes only.

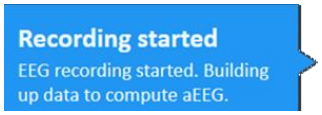
4.10. Alarms and information messages

The **n**ëo monitor software has two types of warning messages:



Alarms:
Attention from clinical staff is required. This includes:

- High electrode impedance
- Amplifier disconnection*
- Non-physiological data detected*
- Bad backup location
- Low disk space
- Too many annotations



Information:
Informative message to explain the current status of the software. This includes:

- Recording started
- Screenshot exported
- Data exported
- Amplifier connected

You can acknowledge the warning message by tapping on it.

***Amplifier disconnection:** If the USB cable gets disconnected, the software shows the message "Amplifier connection error". Recording to the current segment will be stopped and resumes automatically as soon as the amplifier becomes available again, which will be indicated by the information message "Amplifier connected". A special marker will indicate the gap in the recording.

***Non-physiological data detected:** this indicates that the EEG signal is likely out of range of EEG. Multiple causes are possible: very high noise through artifacts, saturated amplifier (the signal sensitivity has to be adjusted in the technical setup) or completely inactive brain signal (refer also to chapter 4.4).

You can switch the message off by tapping it or tapping on **clear messages** button.

4.11. Select a patient

Once a data acquisition session has started, you can create a new patient or assign the session to an existing patient by pressing the **Patient** button on the bottom right corner. Please refer to Chapter 9. In the patient menu, a new patient can be added, or recording can be assigned to existing patient. A search function enables quick patient matching.

For devices connected to a Hospital Information System, active orders are displayed separately.

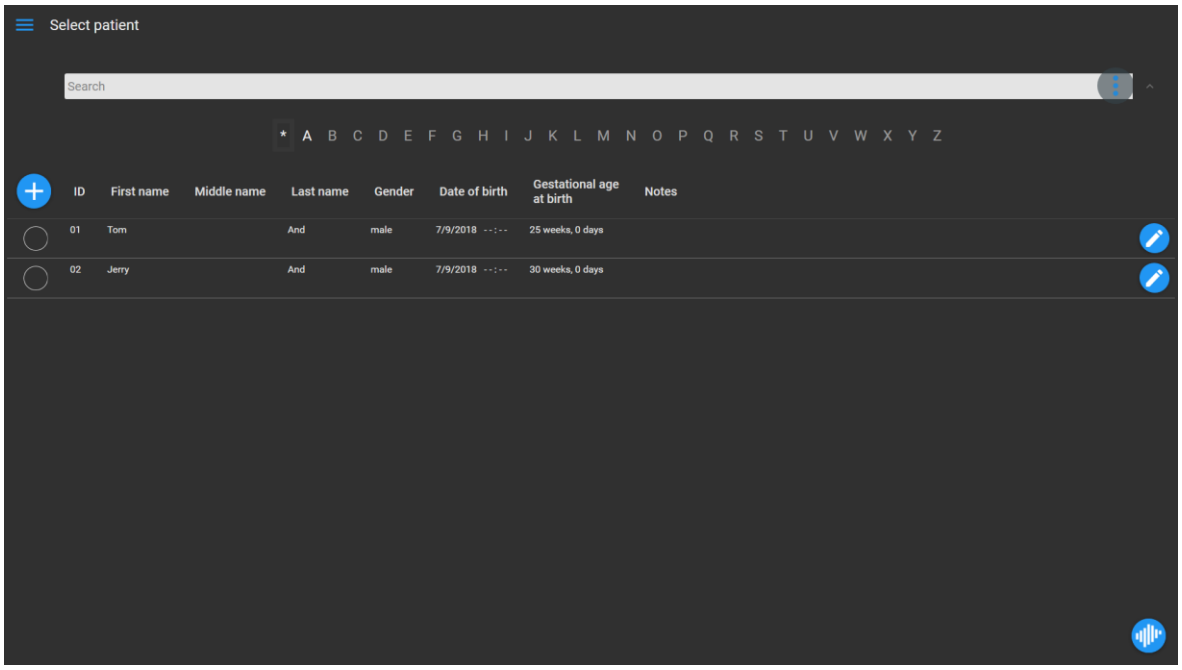


Figure 4-14 Select patient menu

Select search filters.

Add a new patient. A new menu will be opened (Chapter 9).

Edit a patient. A new menu will be opened (Chapter 9).

Return to acquisition.

4.12. Automatic annotation of seizure activity with “SzAssist”

By default, automatic annotation of seizure activity is enabled. It can be disabled in Technical setup by navigating to the section Clinical settings (see also 13.3).

The status of the automatic annotation of seizure activity is indicated by the icon in the lower left corner.

When a suspected seizure event is detected, orange duration annotations will automatically mark the aEEG and EEG data.

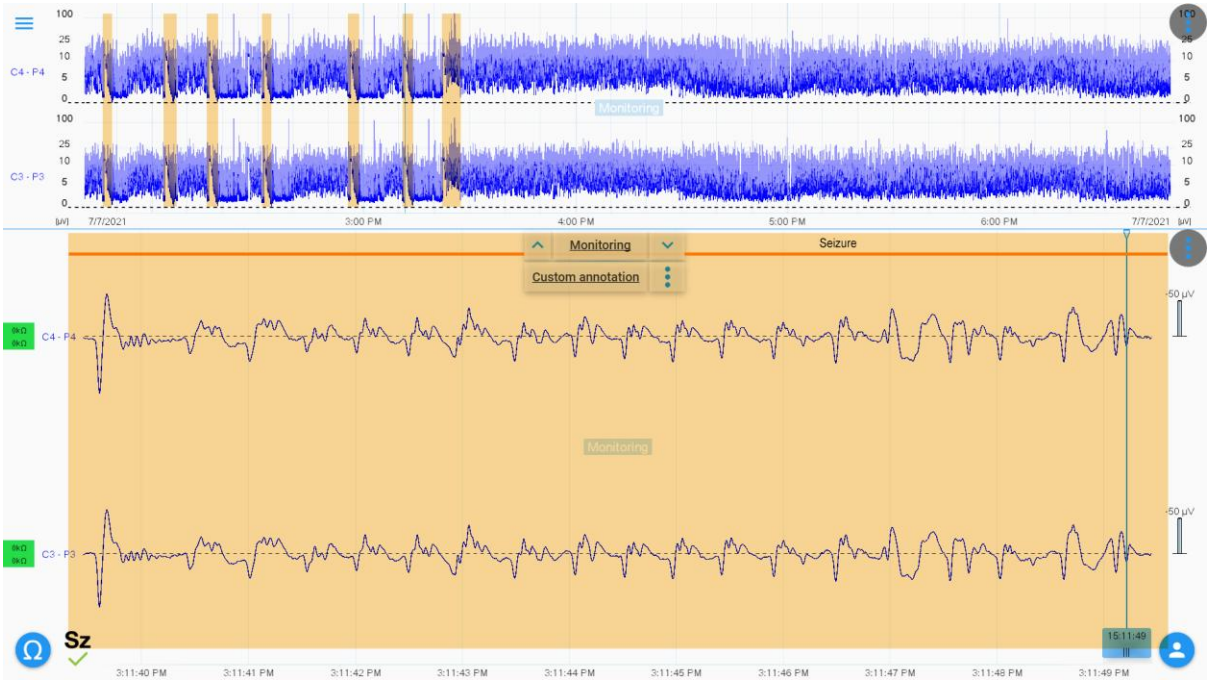
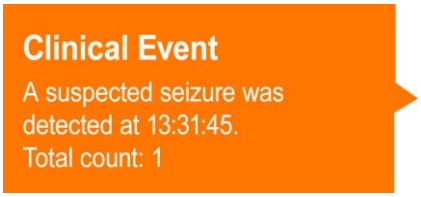


Figure 4-15 Automatic annotations of seizure activity during data acquisition



In addition to the duration annotations, a pop-up message will display indicating the time when the most recent ictal event was detected and a cumulative count of individual suspected seizure events. You can acknowledge the message by tapping on it.

Warning: Artifacts such as handling the patient and patient movement may result in false positives. The **n**ëo monitor software is not a diagnostic device. The seizure detection algorithm **"SzAssist"** is intended to mark sections of EEG/aEEG that may correspond to electrographic seizures. False positives or false negatives can occur. The output of the seizure detection algorithm **"SzAssist"** is intended to assist in post hoc assessment of EEG/aEEG traces by **qualified clinical practitioners**, who will exercise professional judgement in using the information (see also 13.3).

4.13. Stop EEG/aEEG Data Acquisition

After patient registration, the stop button will appear in the bottom right corner. Pressing the **Stop** button finishes the active monitoring session and exits to the start screen.

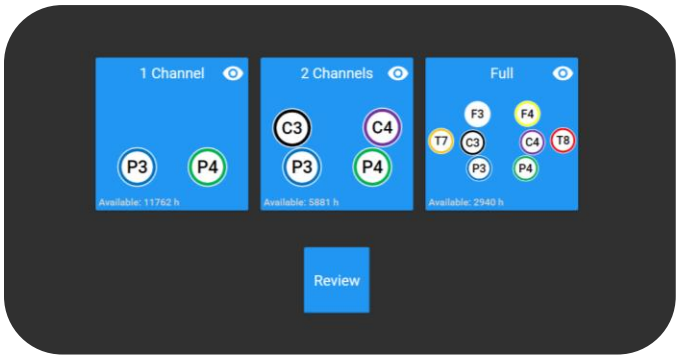
The **n**ëo monitor software prevents stopping a data acquisition session before a patient is selected. Although the **Stop** option is always available in the **Options** menu, you will be presented with a reminder that you must select a patient before ending a data acquisition session.

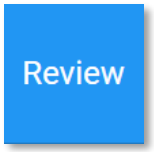
Displayed data in **n**ëo monitor software are always saved into the database. In case the software quits unexpectedly during an acquisition session, the recording will be stopped and stored under the name of the selected patient. In case this happens before the patient selection has taken place, you will be presented with a reminder to assign the unsaved session to a patient when the software is started the next time.

5. EEG/aEEG OFFLINE REVIEW

5.1. Start an offline review session

Using the **n**ëo monitor software, you can review all data that is stored in the local database.





Press the **Review** button on the start screen and proceed to the *Patient* selection screen.

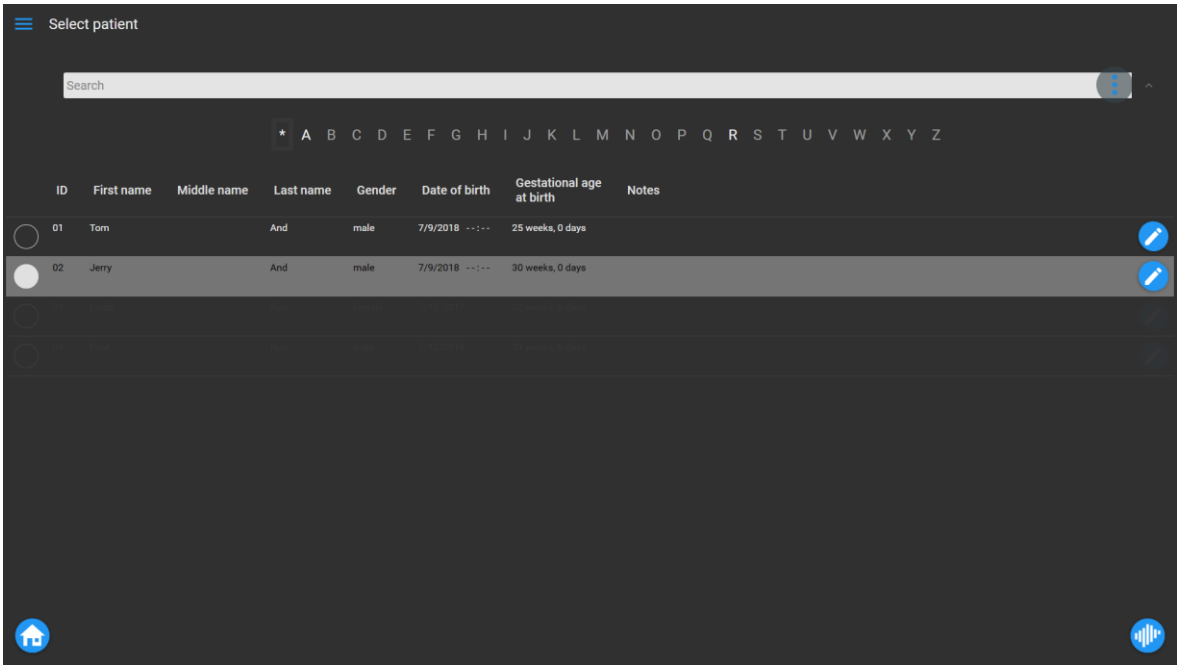


Figure 5-2 Select a patient for review

Tap on the patient whose data you wish to review.

Select search filters.

Edit a patient.

Go to data selection.

Pressing the **Start screen** button in the bottom left corner will take you back to the Protocol selection.

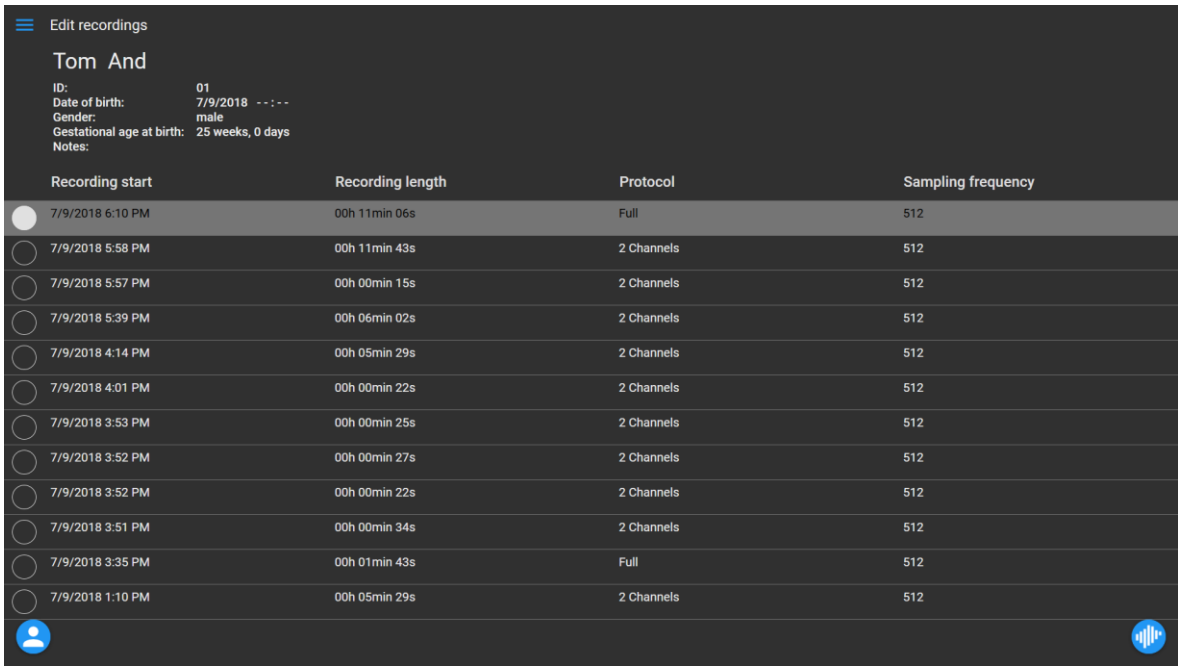


Figure 5-2 Select a session for review

Return to patient selection.

Open selected data.

5.2. Paging through time

During a review session, recorded aEEG and EEG data, impedances and annotations are shown in their respective displays. A blue vertical line indicates the position of the current time cursor. Impedance on the left side depict the values acquired at the beginning and end of the recording.

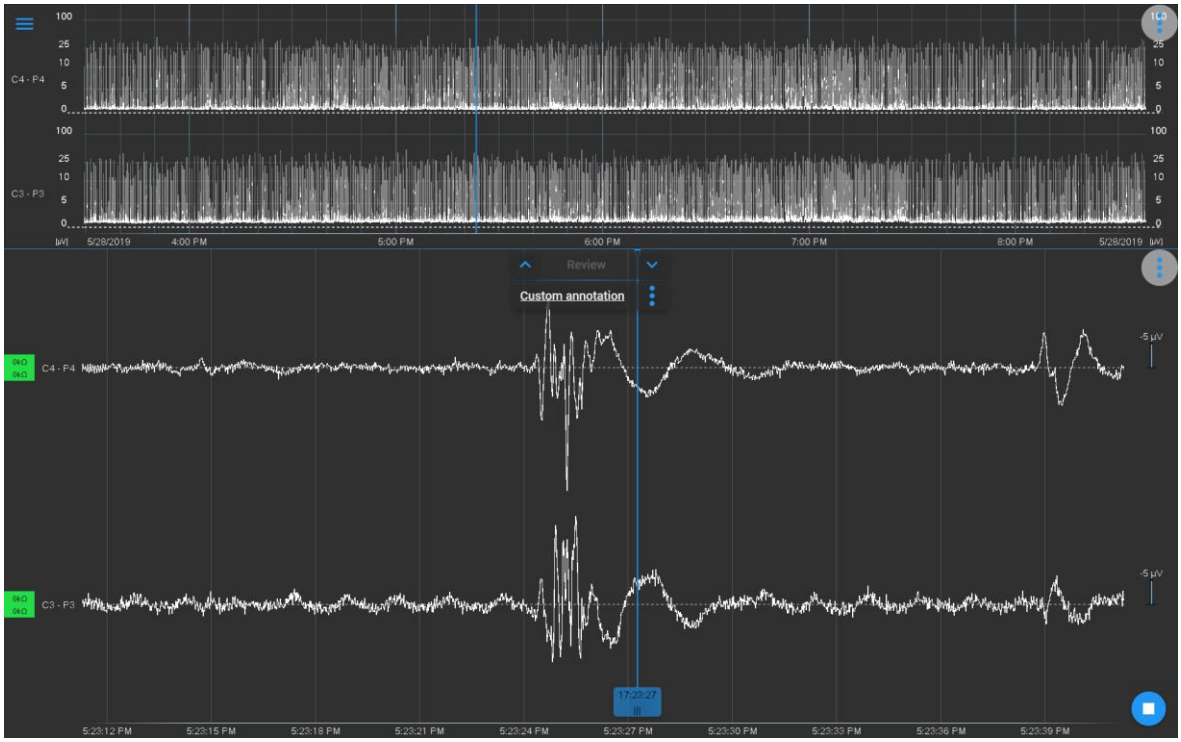


Figure 5-3 Offline review screen

Scroll horizontally in aEEG and EEG view to page through time.
Tap-scroll on the blue time marker to shift its position. Annotations will always be inserted at the current position of the marker.

Single finger tap in aEEG view to jump to a particular time in EEG display.

Pinch or stretch vertically with two fingers to adjust EEG sensitivity in EEG view.
Pinch or stretch horizontally with two fingers to adjust time scale in aEEG or EEG view.

Double tap with two fingers in the EEG view to automatically scroll data. Single finger tap to stop scrolling.

5.3. Open list of events

A list of events can be displayed in a side panel, which can be opened during monitoring, online review, and offline review.

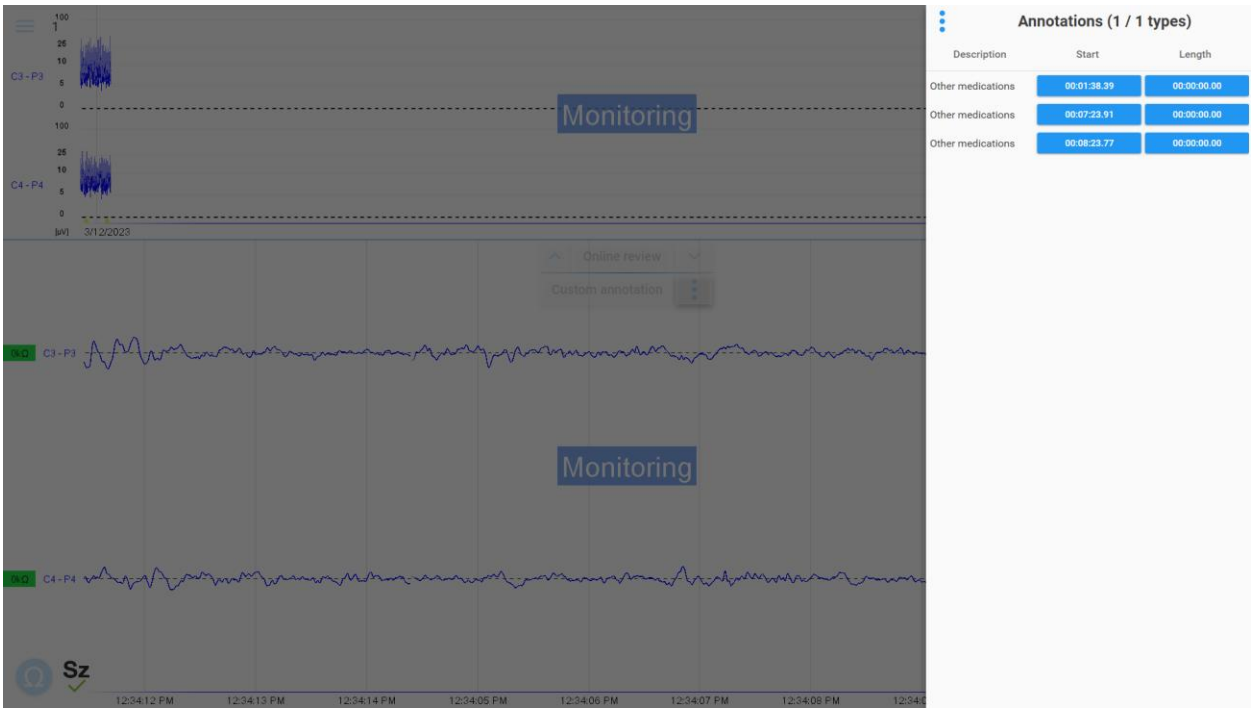


Figure 5-4 Annotation list

Swipe from the far right with a single finger to display the side panel.

Select event type. Individual events are displayed with their start time and length. Selecting an event in the side panel will display the event in the EEG view during review.

Single finger swipe to the right to close the events side panel.

5.4. Stop a review session

Pressing the **Stop** button finishes the review and exits to the start screen.

6. REPORTS

6.1. Create a report

On the Start screen, press **Report**.

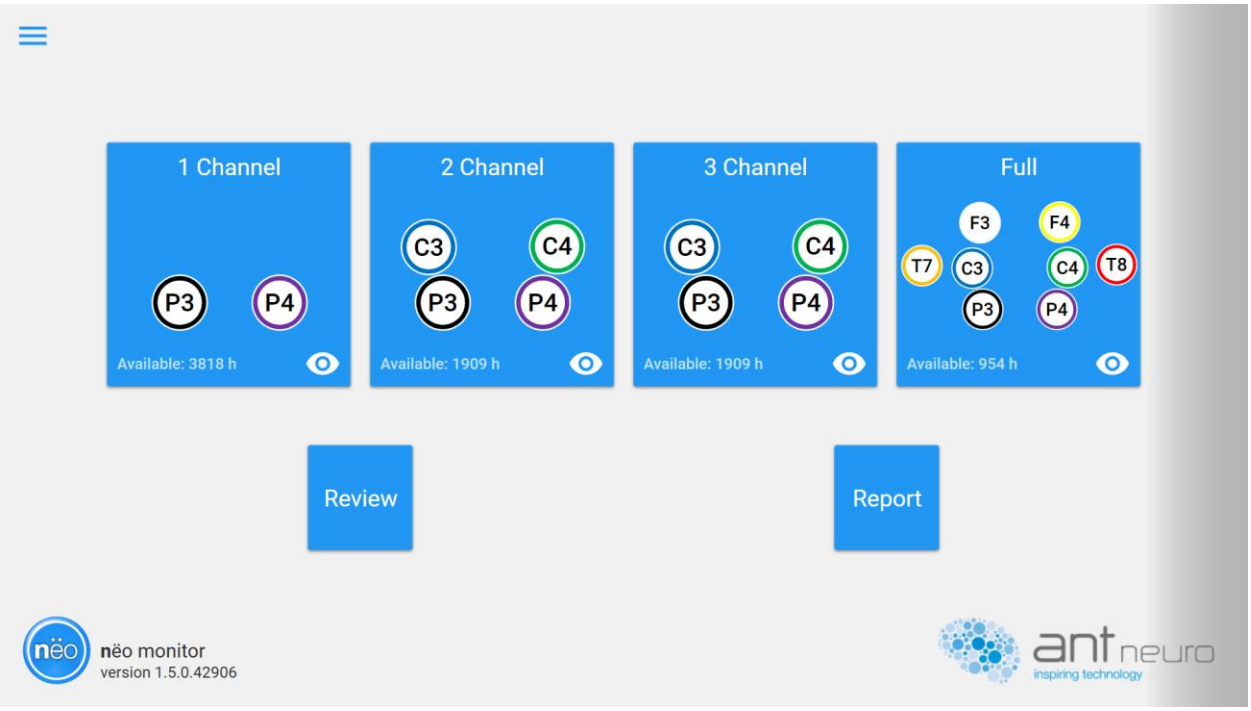


Figure 6-1 Start screen

6.2. Select patient

Select your patient from the list and press the **Orders** button in the lower right corner to proceed to that patient's Report page.

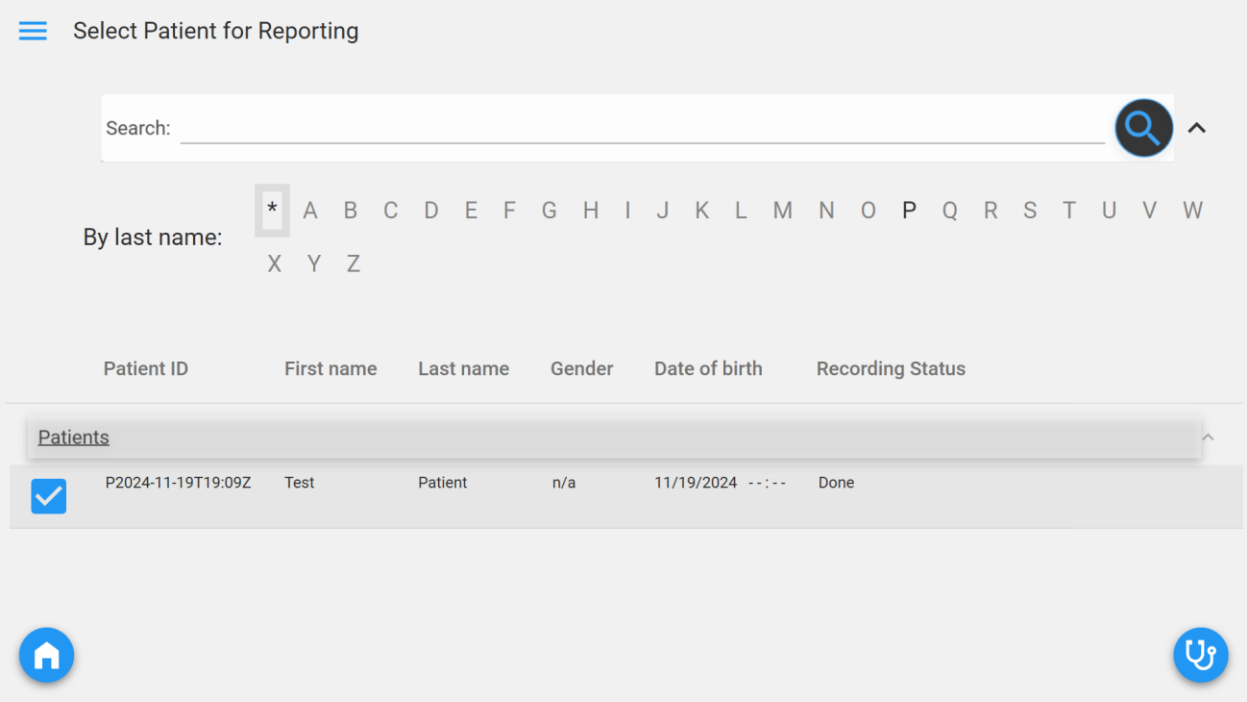


Figure 6-2 Patient list in Report workflow

6.3. Compose, edit or view a report

Start a new report by selecting the plus icon. Existing reports can be edited or viewed depending on their status. A status of:

- Begin = The report is in draft and can be edited
- Sent =The report is finalized and cannot be edited

Multiple reports can be saved for a single patient.

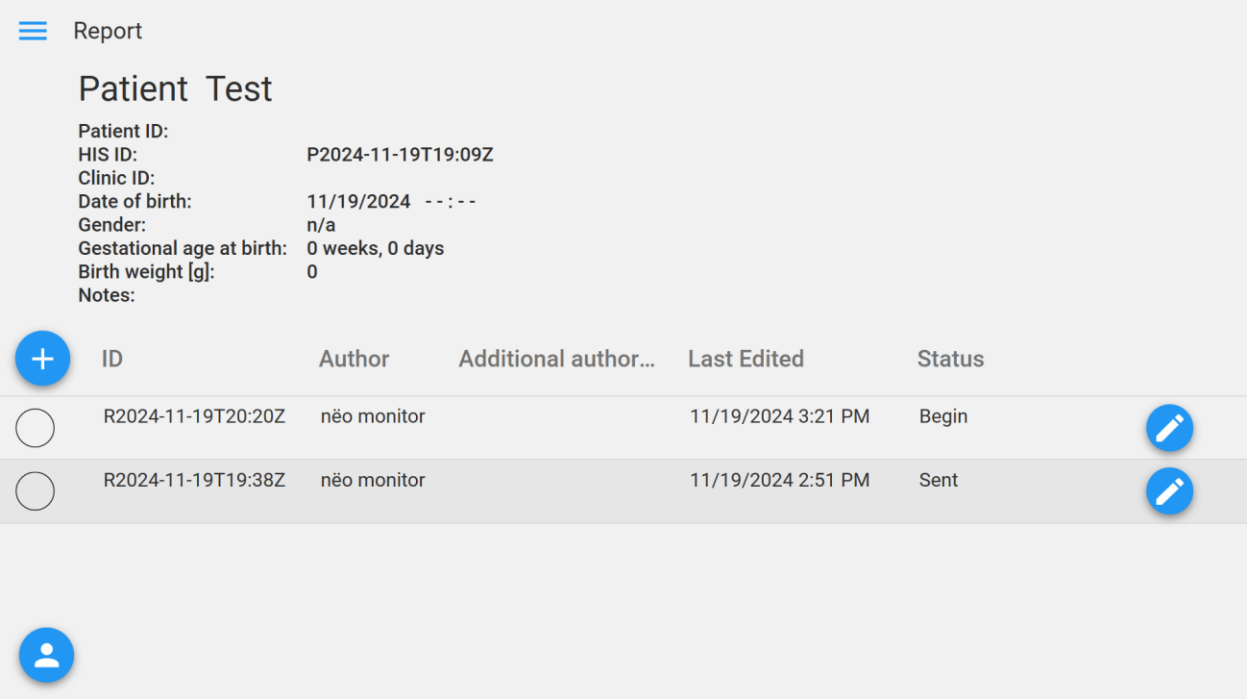


Figure 6-3 Report page for a patient

Enter report details. You must select a recording under **Recording Details** to be associated with the report.

Figure 6-4 Report workflow

Select the **Preview** button in the lower right corner to display the PDF preview.

6.4. Save, finalize or export a report

In the Report PDF preview, you can either return to the draft form, save changes, finalize or export a report.

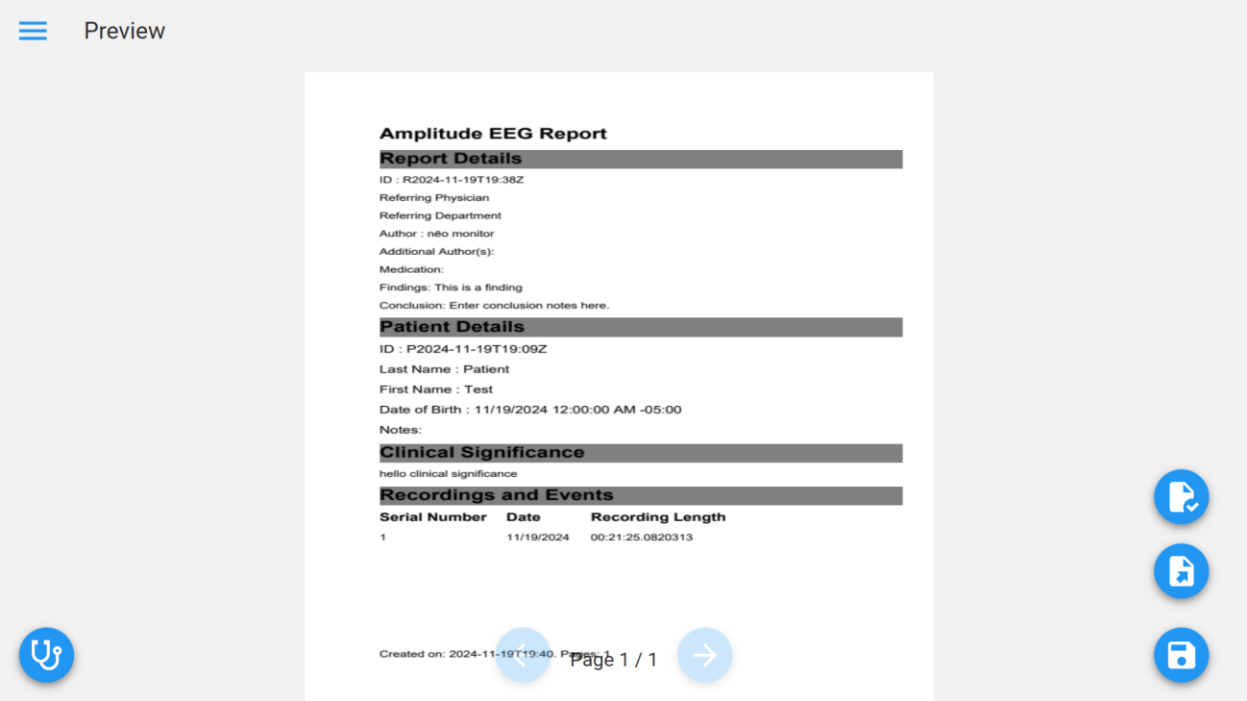


Figure 6-5 Report preview

Return to the report draft form

Finalize the report. Report status will be ‘Sent’ and you can no longer edit the report.

Export the current report version to either export location defined in Technical setup or send to the Hospital Information System, depending on the configuration.

Save changes. Report remains in draft ‘Begin’ status.

7. QUICK ACCESS NAVIGATOR

While in any view of the **n**ëo monitor software, the quick access navigator can be opened via ☰ in the top left corner.

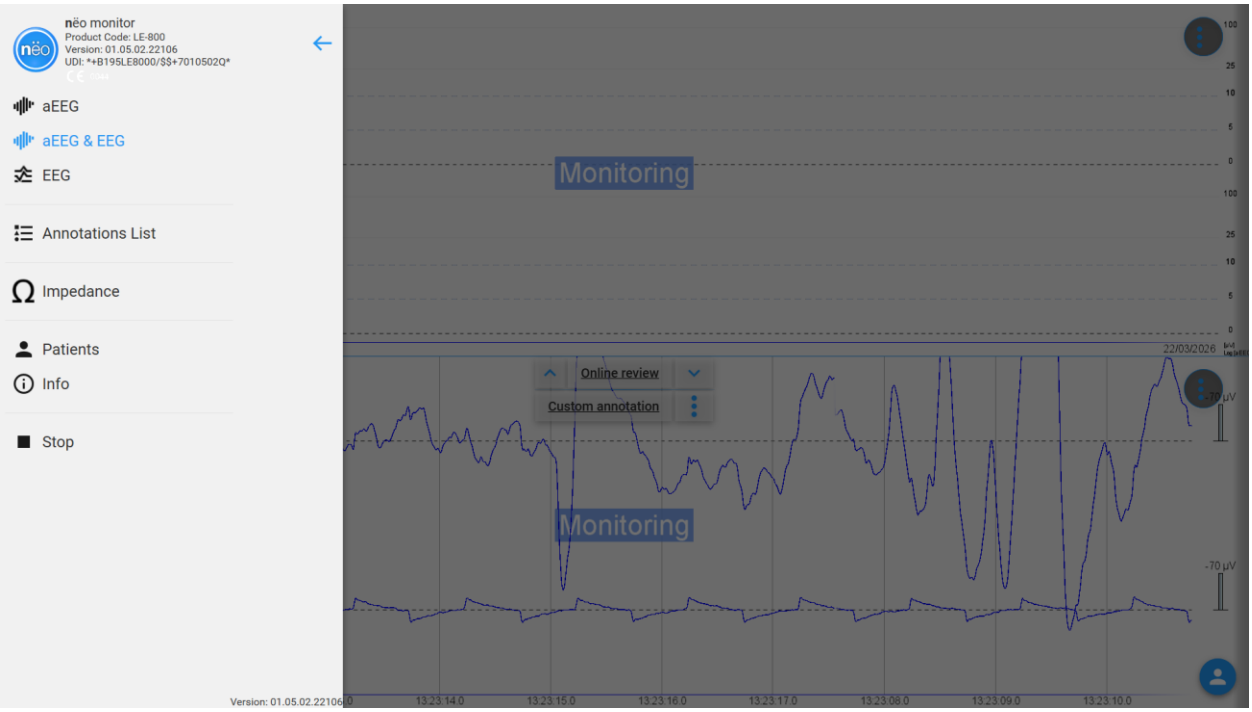


Figure 7-1 Quick access navigator

The accessible menu points are listed below. The currently active view is displayed in blue.

aEEG	Displays the aEEG view only.
aEEG & EEG	Displays the aEEG & EEG views in one screen.
EEG	Displays the EEG view only.
Annotations List	Opens the Annotations List
Impedance	Activates the Impedance view.
Patients	Activates the Patient Management screen.
Info	Shows the current session information.
Export	Allows the export of the complete EEG and aEEG data including annotations in an importable format. Data are exported onto a USB drive or custom (network) path, depending on the options chosen in

	the Technical setup workflow. Data are exported as anonymous or with patient name and ID, depending on the options chosen in the Technical setup workflow.
■ Stop	Exits the current recording or review.

Further options are only available if the quick access navigator is opened in the start screen:

Technical setup	Initiate the Technical setup screen. Password inquiry will pop up.
Quit	Quit **n**ëo monitor software and proceed to shut down PC.

8. DATA EXPORT and BACKUP

8.1. EEG/aEEG export

During an offline review session, export functions are available via ☰ in the top left corner.

Export	Export complete EEG and aEEG data in an importable format (CNT, EDF+ or ASCII) onto a NTFS formatted USB or network drive. By default, the name of the exported file is defined by the name of patient, the start and ending time of the data to be exported, and the type of the data (aEEG, raw EEG or filtered EEG). Entire data from the beginning to the end will be exported.

The Technical setup workflow allows the user to define settings for export location (USB or network drive), data format and data anonymization. Further, it allows customization of the type of EEG data to be exported (filtered and / or raw EEG).

8.2. Text Conversion in Exported Data

Data exported from **n**ëo monitor is designed to be used with external software tools. To ensure compatibility with a wide range of applications—including older systems— **n**ëo monitorconverts all text in exported data to basic English characters.

Specifically:

- Special characters or non-English letters may be changed or removed.
- Some characters may be replaced with several letters. For example, the character “北” is exported as “Bei”.

This conversion follows fixed rules and does not take word meaning or context into account. As a result, the exported text should not be considered a translation of the original content.

Because of this process, the exported data and metadata (files with additional information) may not exactly match the original information stored in **n**ëo monitor, including annotations and patient-related text.

We recommend reviewing exported files and their metadata carefully to ensure they meet the requirements of your intended use outside of **n**ëo monitor.

8.3. Database backup

The Technical setup workflow provides the option to back-up the entire database onto an external hard drive, connected to the USB port. The back-up drive needs to be NTFS-formatted. Please make sure that there is sufficient free storage available on the back-up drive. We recommend at least 250 GB for each backup. To restore a backup, please contact support. Note that restoring a backup will overwrite the existing database.

9. PATIENT MANAGEMENT

In the **n**ëo monitor software, each recording is linked to a unique patient. Each patient is entered into the software with a collection of demographic information listed below.

Mandatory information:

- Patient ID: An identification number of the patient defined by the hospital
- First name: One or more first names of the patient
- Last name: The last name (surname or family name) of the patient
- Date of birth: Date of birth of the patient (the date is formatted according to the language settings in the Technical setup workflow)

Note: Each field allows for a unique combination of alpha numeric and special characters.

Optional information:

- Time of birth: Time of birth of the patient (hh:mm)
- Gender: Gender of the patient
- Gestational age at birth: number of weeks and days from the first day of the mother's last menstrual cycle to the birth date
- Notes: Further patient details can be entered into Notes.
- Birth weight: weight of the baby at birth.

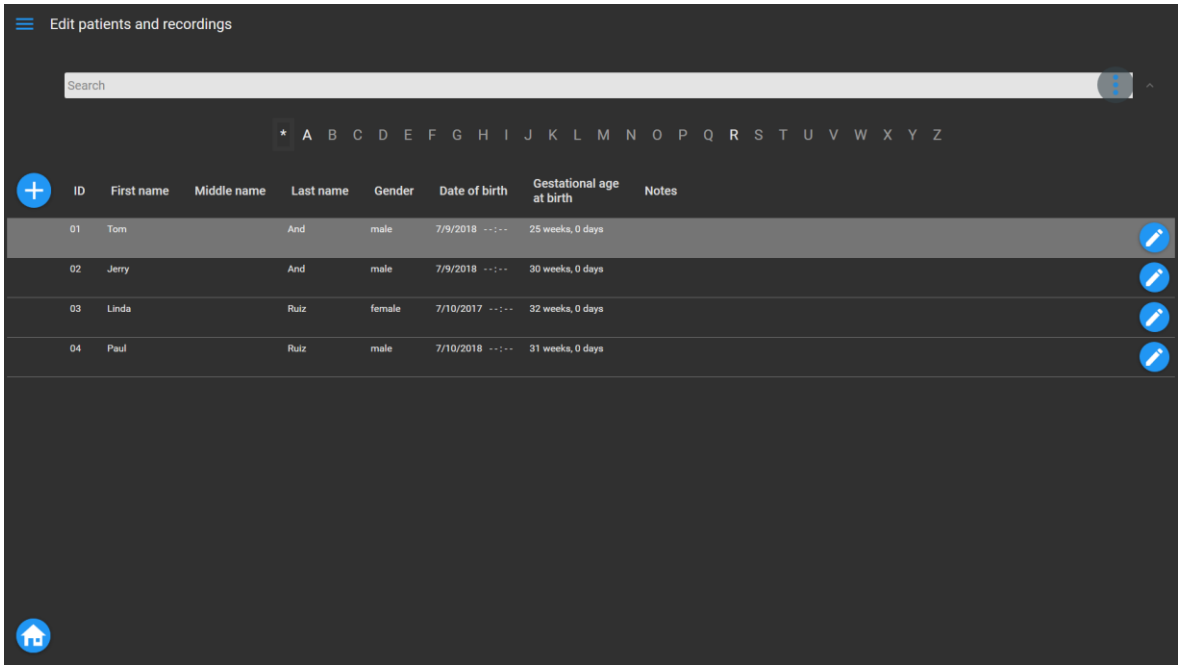


Figure 9-1 Patient selection menu

The patient database is accessible:

1. from the start screen via the quick access navigator in the left top corner.
2. during a recording via the patient button on the right bottom corner.

3. before review mode, right after pressing on the review button in the start screen.

Depending on the entry point to the patient database, different buttons are enabled.

Select search filters. The search field at the top of the screen allows you to search the table. A list of filters is available by pressing the 3-dots ellipsis button.

Add a new patient.

Edit a patient.

Go to data selection.

Press the **Signal** button on the bottom right corner. You will be directed to a new page, where demographic data of the selected patient is shown on the top, and recording sessions associated with that patient are listed on the bottom.

Pressing the **Start screen** button in the bottom left corner will take you back to the Protocol selection.

The alphabetic bar filters for patients whose first name start with a particular letter. The * button at the leftmost of the list deactivates this filter.

9.1. Create a new patient or modify an existing patient

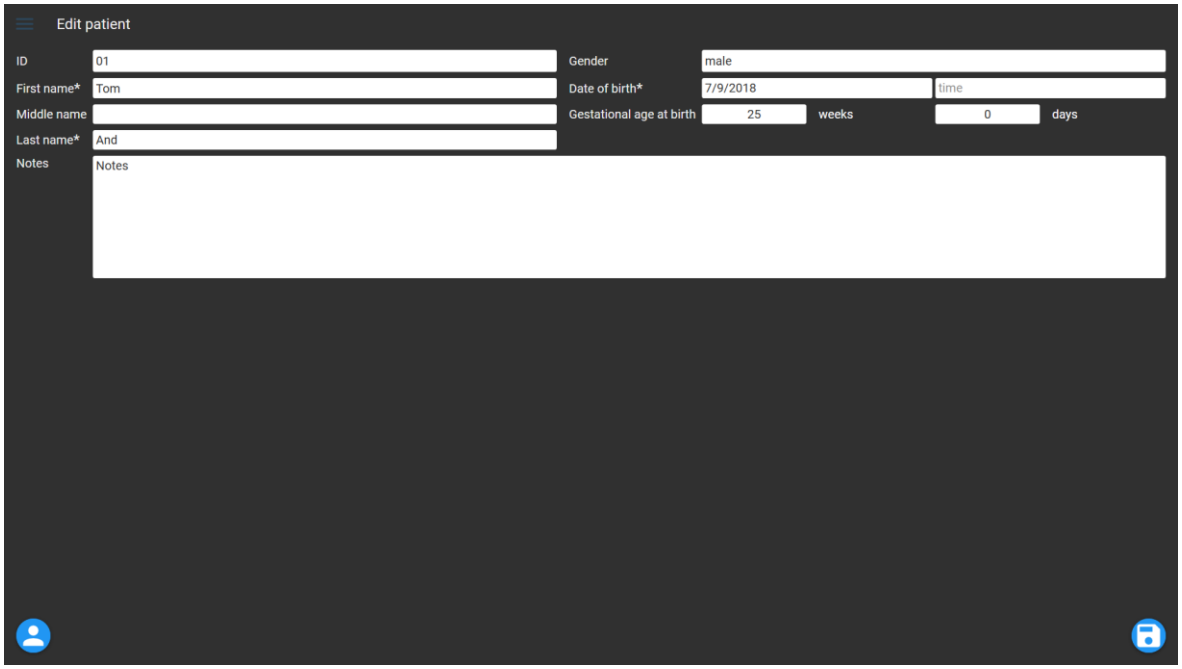


Figure 9-2 Patient edit menu

Return to patient selection without saving.

Save patient data and return to patient selection.

After patient selection, the name of the selected patient will be indicated on the top left corner of the *Acquisition* screen.

9.2. Merge patient

To merge a locally created patient with a Hospital Information System (HIS) record, select the local patient in the patients list ('Manage Patients and Recordings' in Technical Setup). Click the 3-dot menu on the top right and select "merge into HL7 patient". This opens a dialog box with all HL7 patients available for merging. Select an HL7 patient from the dropdown menu and click "Okay". This will remove the local patient record and merge all linked data with the HL7 record.

For merging:

1. Go to 'Manage Patients and Recordings' in Technical setup
2. Select a local patient, click the 3-dot or ellipsis drop down menu

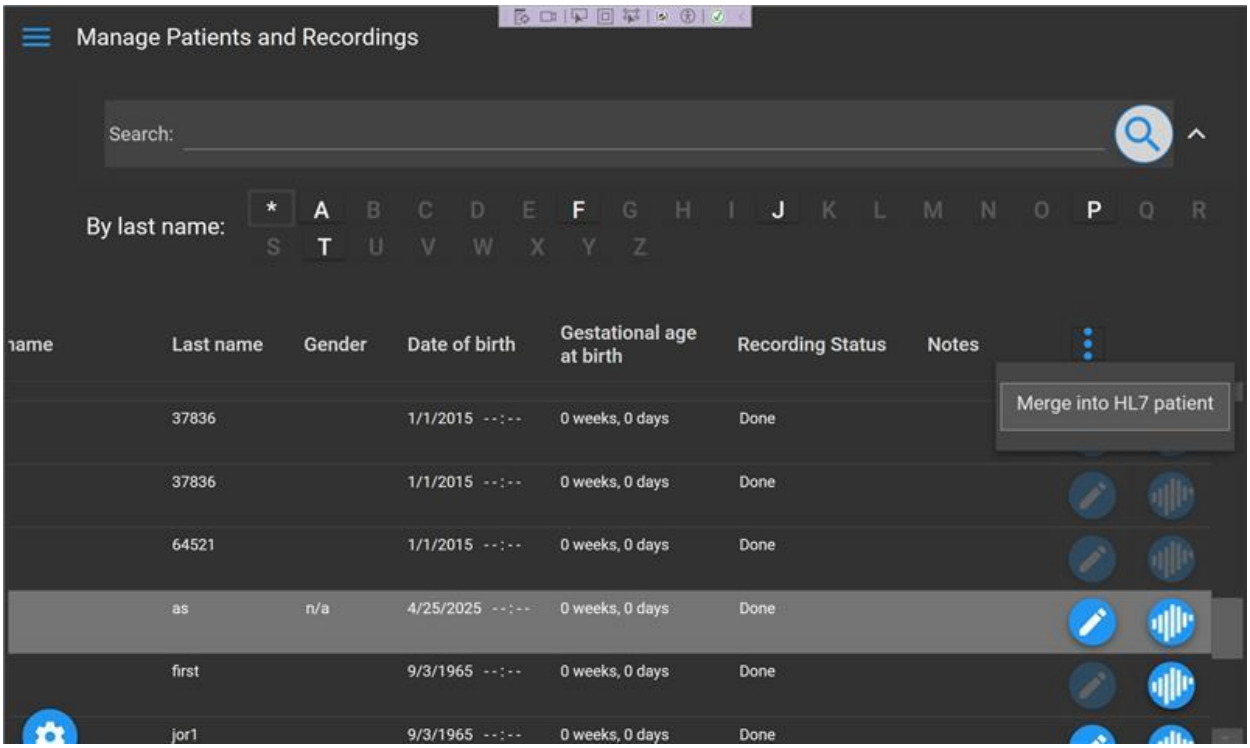


Figure 9-3 List of patients under Manage Patients and Recordings

3. Select HL7 patient, click 'Okay'

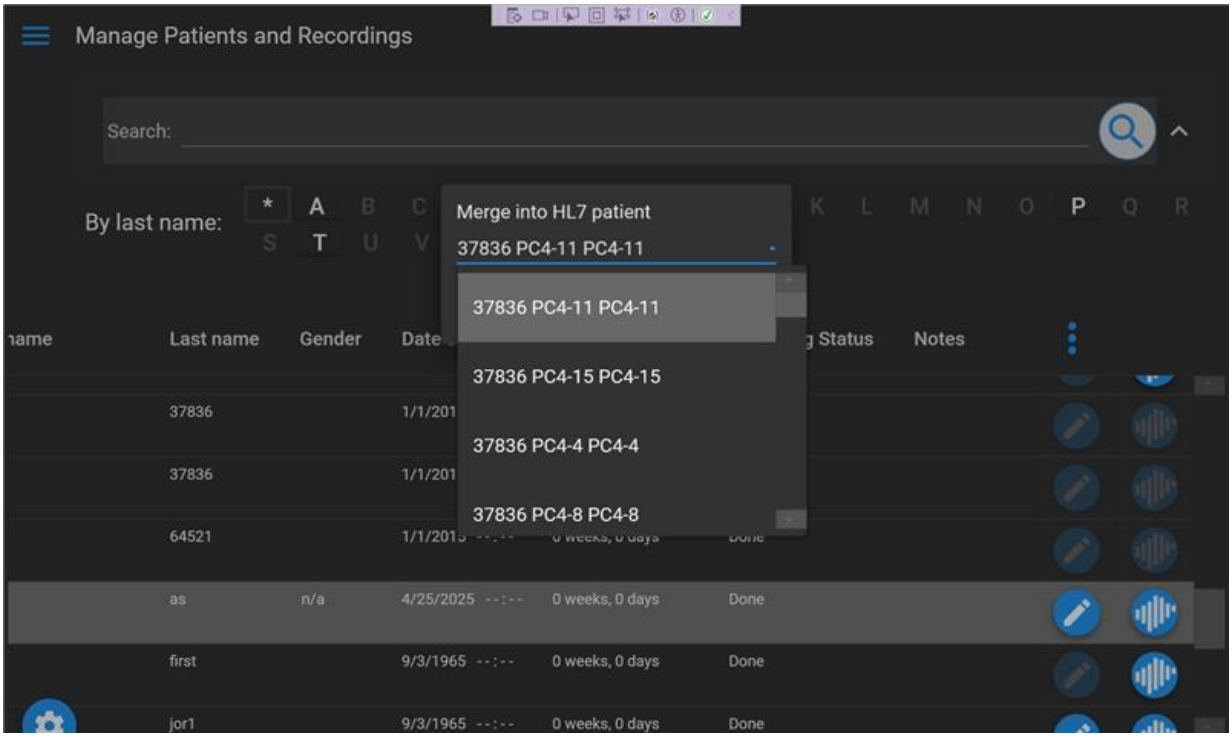


Figure 9-4 Merging patient records

10. INFO FUNCTION

During a recording with **n**ëo monitor software, help can be accessed via ☰ at the top left corner.

ⓘ Info	Show current session information (patient information and montage of the protocol).

11. EXIT MONITORING and SHUT DOWN

Use the 'Quit' button from the quick access menu to quit the **n**ëo monitor software .

⏻ Quit	Quit **n**ëo monitor software

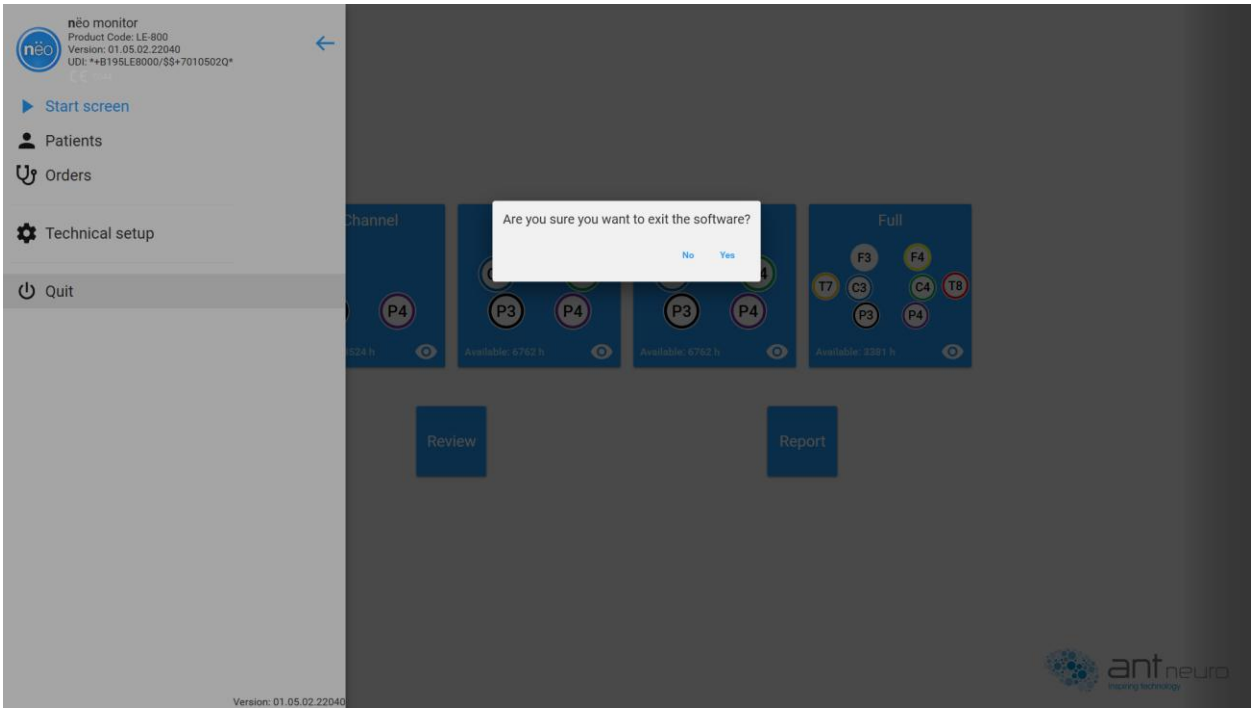


*Figure 11-1 Confirmation to exit the **n**ëo monitor software*

Subsequently, there will be a prompt to either restart the **n**ëo monitor software or shutdown the PC.

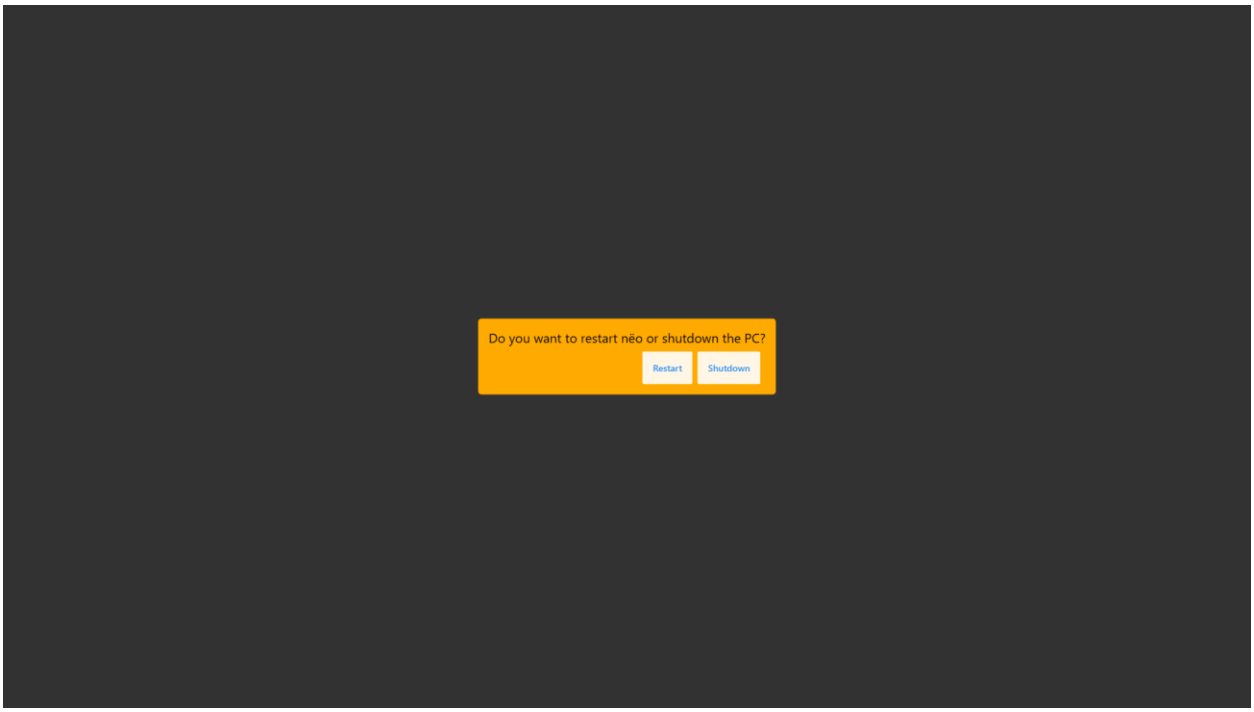


*Figure 11-2 Confirmation to restart the **n**ëo monitor software or shutdown the PC*

The device can now be powered off with the hardware switch on the right side of the monitor and unplugged.

12. CARE and HYGIENE

The medical grade computers are mechanically robust. We recommend keeping the electronic components a minimum distance of 1.5 m from the patient and to protect them from direct contact with potential contaminants. Please take special care of the connector openings and switches on the device, avoiding contamination.

The computer unit cannot be sterilized.

If switched on, features of the operating panel or the optional touch screen can be triggered unintentionally, for example, due to water drops.

Only the wipe disinfectants that are listed below can be used for cleaning the unit.

The active substances in the following table are expected to be harmless for the unit if the listed limits are observed. The table does not represent a medical evaluation of the effectiveness of these substances.

Active Substance	Max. Concentration in %	Max. Exposure in Minutes	Example Products
Alcohol	100	360	Bacillol AF Meliseptol
Biguanide	8	360	Incidin Plus
Chlorine, organic or inorganic substances with active chlorine	10	360	Incidin perfekt Optisept
Per-compounds	8	360	Incidin active Terralin PAA
Phenol or phenolic derivates	6	360	Helipur

The following detergents and agents are unsuitable for cleaning.DO NOT USE PRODUCTS CONTAINING:
- acetone
- citric acid
- cleaning liquids basing on crude oil like petroleum, turpentine, or oil

Using cleaning pads, rough sponges and cloths might damage surfaces and sealing material.

Cleaning instructions for **w**aveguard original caps and related-accessories (e.g. adapter) can be found in the **w**aveguard original user manual.

13. TECHNICAL SETUP

The **nëo™ monitor** software has a workflow called “Technical setup” that contains all software configuration parameters. The Technical setup is accessible from the start screen via the quick access navigator in the left top corner. It is password protected. Please see section 1.6 System and data protection for details and APPENDIX C. NËO monitor software Technical setup Default Settings.

Figure 13-1 Technical setup menu

Pressing the **Start screen** button in the bottom left corner will take you back to the start screen. Pressing this button in a sub-section will return you to the Technical setup menu without saving changes.

In each sub-section, save changes and return to the Technical setup menu.

13.1. General settings

The language, units, impedance and signal quality settings, filter settings and export settings can be defined under General settings.

Figure 13-2 General settings menu

13.2. Display settings

The background color or color theme, view settings such as greyscale option and EEG sensitivity, screen calibration, and privacy or anonymization options can be defined under Display settings.

Figure 13-3 Display settings menu

13.3. Clinical settings

13.3.1. Automatic seizure detection with “SzAssist”

The option to enable automatic annotation of seizure activity and its estimator threshold can be defined under Clinical settings.

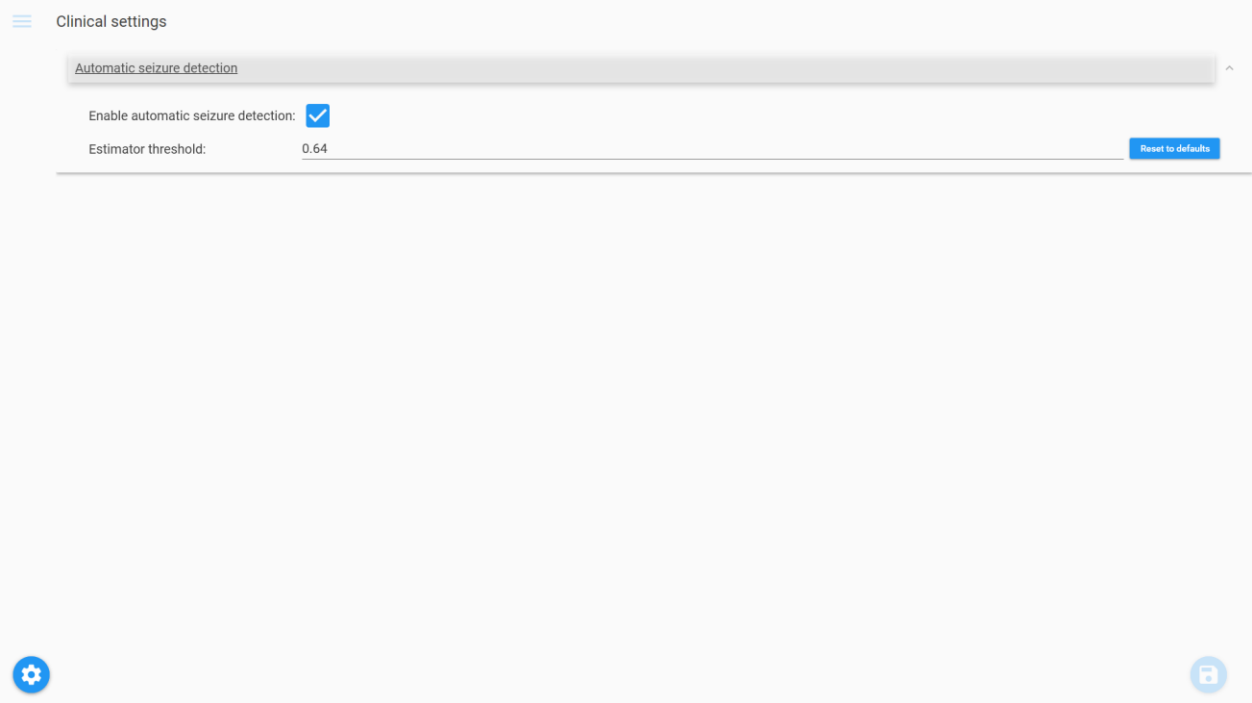


Figure 13-4 Clinical settings menu

The **Estimator threshold** specifies a decision boundary differentiating between classifying successive epochs as a seizure event or non-seizure event. A minimum threshold of **-3** leads to most detections ("sensitive setting"), and a maximum threshold of **3** will result in fewer detections.

The seizure detection is based on the calculation of ‘likelihood matrices’ from 21 characteristics of the EEG into a ‘hyper-parameter’; subsequently, the median likelihood from several consecutive epochs (length 32 seconds, overlap 4 seconds) is compared to the threshold. The method and default boundary (median $\geqslant$ 0.64) as in the **Clinical settings** configuration page is derived from *Tapani et al. 2019* *.

Note: The channel selection is configurable, which will influence the results and should only be done by a knowledgeable user. Examples are C3-P3 and C4-P4 or C3-O1 and C4-O2.

* *Tapani, K. T., Vanhatalo, S., & Stevenson, N. J. (2019). Time-Varying EEG Correlations Improve Automated Neonatal Seizure Detection. International journal of neural systems, 29(4), 1850030.* https://doi.org/10.1142/S0129065718500302

The performance of the implemented seizure detection method depends on the setting of the **Estimator threshold and the selected channels**. Typical performance is characterized by: Specificity of 50-86%, Sensitivity of 98-100%, and a Precision of 72-100%, Negative Predictive Value of 97-100%.

13.3.2. BSR/IBI indicators

For the **BSR** and **IBI** display in the aEEG view, the EEG is categorized into periods of suppression, bursts, and continuous EEG/artifact. The BSR and IBI provide a convenient and condensed view of the related phenomena, as additional technical indicator derived from the EEG to support healthcare professionals in their clinical assessment. In the context of EEG/aEEG in neonates, it is relevant to note that 'bursts' are also called SATs (spontaneous activity transients)**.

In the **n**ëo monitor software the burst algorithm uses a *non-linear energy operator* that combines both amplitude and frequency content of the EEG signal. The EEG is filtered into two frequency bands (EEG band and artifact band), from which the method calculates a smoothed value in a 1-second sliding window. If the value in the EEG band exceeds the predefined 'burst threshold' for at least 1 second (after suppression) or 2 seconds (after artifact/continuous EEG), the EEG is classified as burst. If the same value stays below the 'suppression threshold' for a minimum of 2 seconds, then EEG is classified as suppression. The method and thresholds are based on the 'revised' algorithm by *Palmu et al. 2010***.

*** Palmu, K., Wikström, S., Hippeläinen, E., Boylan, G., Hellström-Westas, L., Vanhatalo, S. Detection of 'EEG bursts' in the early preterm EEG: visual vs. automated detection. Clin Neurophysiol. 2010 Jul;121(7):1015-22.* https://doi.org/10.1142/S0129065718500302

13.4. Edit patients and recordings

Patient demographic information and their recordings can be edited and deleted under the Edit patients and recordings.

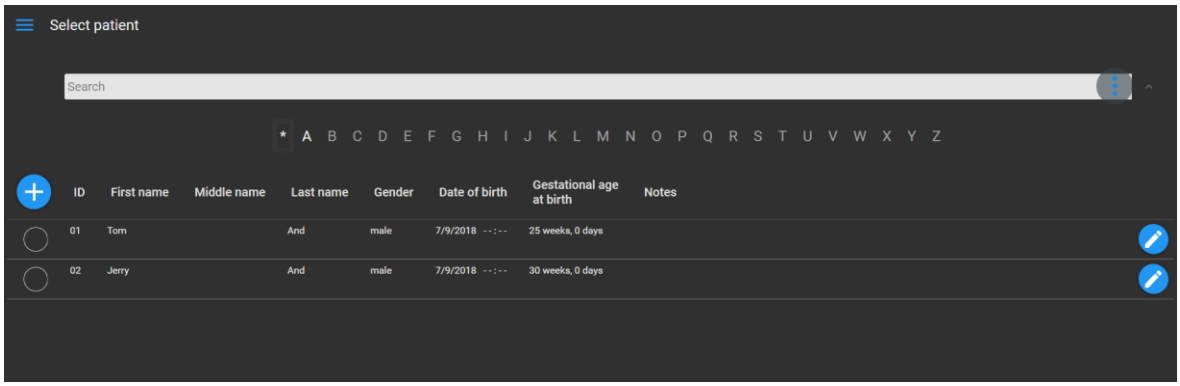


Figure 13-5 Patient selection menu

13.5. Edit hardware setups

Amplifier setup can be defined under Edit hardware setups.

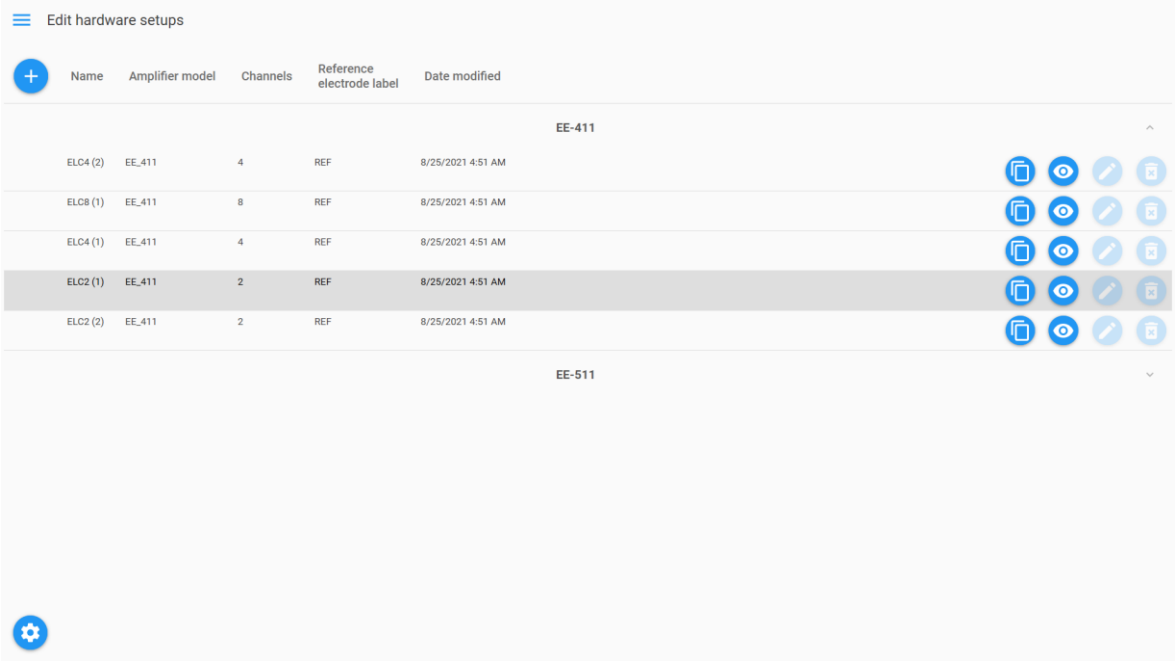


Figure 13-6 Edit hardware setups menu

13.6. Edit montages

Montages can be created and edited under Edit montages.

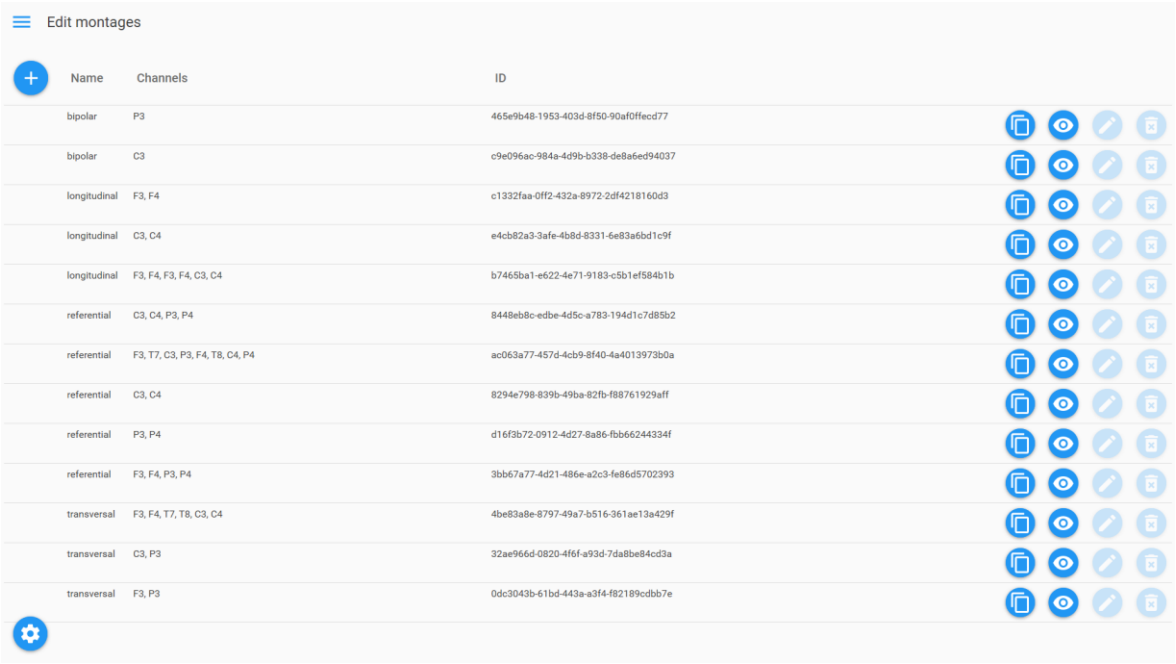


Figure 13-7 Edit montages menu

Note: It is optional to configure REF electrode as an active channel.

13.7. Edit protocols

Options for creating, editing, and enabling protocols can be defined under Edit protocols.

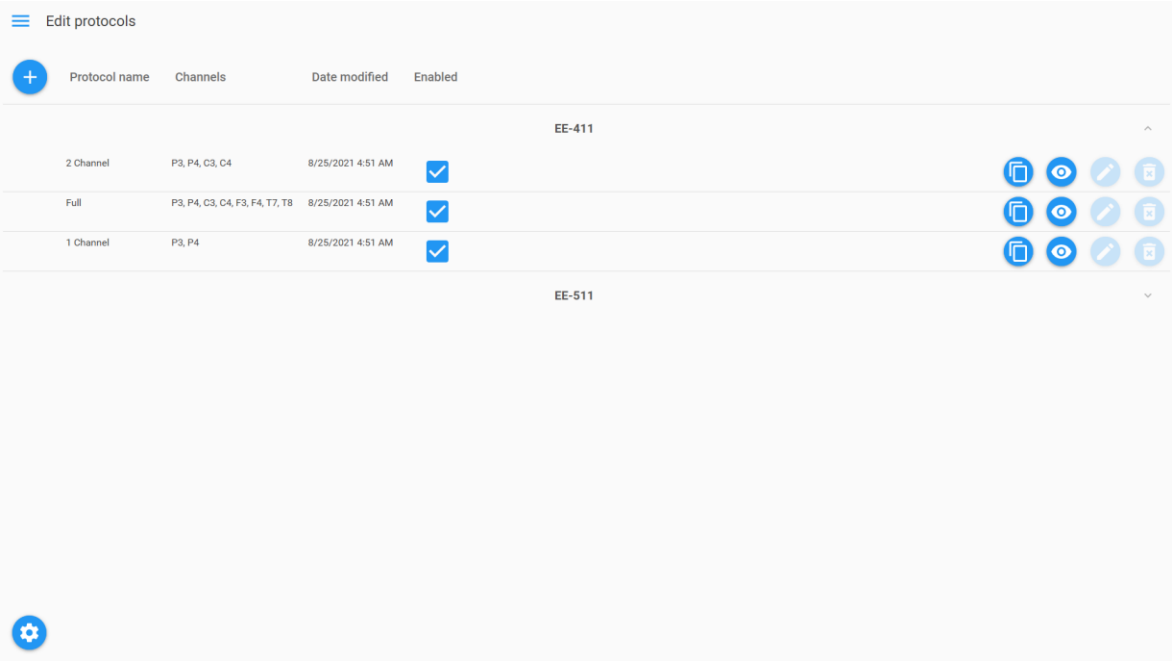


Figure 13-8 Edit protocols menu

13.8. Annotations

The option to enable annotations, define colors and edit the default list of annotations can be done under Annotations.

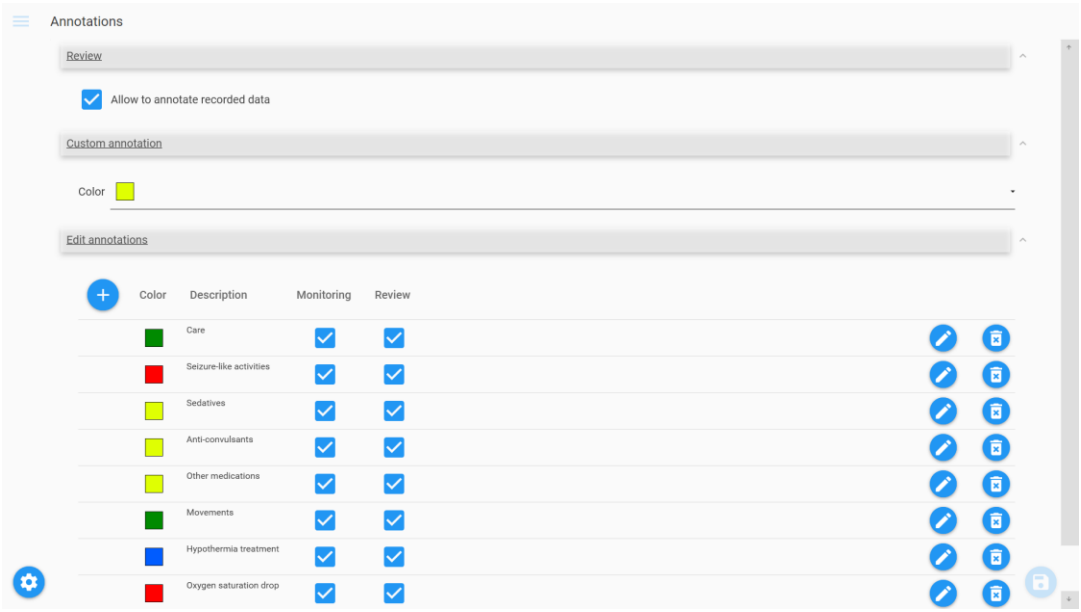


Figure 13-9 Annotations menu

13.9. Maintenance

Resetting passwords for setup and review, deleting all patient data, creating a backup, and enabling notifications regarding data validation can be done under Maintenance.

Figure 13-10 Maintenance menu

After each recording, a validation is conducted to ensure data is consistent. If the validation is not successful, a notification will display. This notification can be acknowledged by tapping it away. For users who are exporting data often, we recommend that the notifications be enabled. If you encounter issues with exporting data or are receiving these notifications, please contact your local distributor.

APPENDIX A: ESSENTIAL PARAMETERS

a) EEG data recording

During EMC testing the essential performance was monitored based on the criteria below.

- Accuracy of signal reproduction: signal reproduction of a 6Hz triangular signal with 1mVpp is within ±20% of the input signal or ±10 µV, whichever is greater.
- Input noise: peak to peak input noise voltage under short circuit load condition is below 6µVpp with 50Hz low pass filter applied.
- Frequency response: The output for sine wave signals at 0.5Hz and close to 50Hz (outside notch filter range to suppress 50Hz) is within 71% to 110% of the output obtained for a 5Hz sine wave signal.
- Common mode rejection: Sine wave common mode signal applied with 1Vrms results in less than 100 µVpp signal for frequencies in the range of 50Hz to 60Hz.

b) Accuracy of aEEG computation

At given frequencies, deviation from expected aEEG value is smaller than 2% of input amplitude peak-to-peak voltage or 10% of expected aEEG value (whichever is greater). The following table lists the expected aEEG values and acceptable deviations for sine wave input signals of 100µVpp. Note that for sine wave input signals of the given frequencies, the upper and lower value of the expected aEEG are identical.

Frequency (Hz)	Expected aEEG value (µV)	Min (µV)	Max (µV)
2	23	20.7	25.3
10	100	90	110
14	100	90	110
25	14	12	16

APPENDIX B: NËO MONITOR TECHNICAL SPECIFICATIONS (EMC)

The compliance in the tables below is valid for *nëo monitor system ES-820* consisting of:

Part	**Cable length (m)** (total length must remain < 3 m)
nëo monitor EEG/aEEG software LE-800	-
ACL All-In-One PC	-
eego amplifier EE-411 / EE-511	0.6
Breakout adapter XC-810 / Adapter XC-425	1.8
Cart XC-820/XC-830	-

Guidance and manufacturer's declaration – electromagnetic emissions		
The nëo monitor system ES-820 *is intended for use in the electromagnetic environment specified below. The customer and/or user of the system should ensure that it is used in such an environment.*		
Emission Test Compliance	Compliance	Electromagnetic Environment - guidance
RF Emissions CISPR 11	Group 1	The *nëo monitor system ES-820* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The *nëo monitor system ES-820* is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration – electromagnetic immunity			
The nëo monitor system ES-820 *has been tested as compliant according to standards as indicated below.*			
Immunity Test Standard	Compliance test level		Electromagnetic Environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air		Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Uin - 100% dips: 10 ms / 3x per phase/ 20s Uin - 100% dips: 20 ms / 3x per phase/ 20s Uin - 30% dips: 500 ms / 3x per phase/ 20s Uin - 100% dips: 5000 ms / 20s		(During and after the test function was as intended) Mains power quality should be that of a typical commercial or hospital environment. (Test of 0 V / 5 s stops function; manual restart OK)
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V rms (0.15 MHz – 80 MHz) 6 V rms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz		The use of portable and mobile RF communications equipment can adversely affect the recording; do not use an operating cellular phone within 30 cm (12 inches) of the amplifier, the cables and the electrodes to avoid excessive noise on the signals.
Radiated RF electromagnetic fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz		
Radiated RF electromagnetic disturbances IEC 61000-4-3	Test freq. (MHz)	Immunity Level (V/m)	
	385	27	
	450	28	
	710-780	9	
	810-930	28	
	1720-2450	28	
	5240-5785	9	

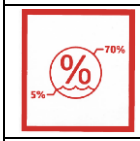
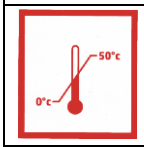
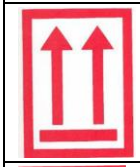
APPENDIX C. NËO monitor software Technical setup Default Settings

Birth weight units	Grams
Electrode type	Always ask
Artifact sensitivity	Low
Automatic impedance check	Enabled
Automatic impedance check Time interval [min]	10 minutes
Threshold impedance input	30kOhm
Low-cut frequency [Hz]	0.3 Hz
High-cut frequency [Hz]	30 Hz
Notch frequency [Hz]	Undefined
Export data	Filtered and referenced
EEG export file format	EEProbe 64bit extended (*.cnt)
aEEG export file format	EEProbe 64bit extended (*.cnt)
Export location	External USB storage
Color theme	Dark
Greyscale display for aEEG	Enabled
Default EEG sensitivity [µV]	70 µV
Automatic seizure detection **"SzAssist"**	Enabled
Automatic seizure detection threshold estimator	0.64
Allow to annotate recorded data	Enabled
Data validation notifications	Disabled

Note: The Technical setup is to be reviewed upon installation and adjusted according to the end users' needs. Depending on the local preferences, additional settings might be adjusted.

APPENDIX D: EXPLANATION OF SYMBOLS

	Manufacturer symbol: indicated with name, address
	Catalogue number
	Model number (e.g., country specific power cord)
	Serial number
Tsn	Tracking number for USB stick (containing the nëo monitor software)
	Year of manufacture
	Conformité Europeenne, CE mark, with number of Notified Body involved in the conformity assessment
	Follow the instructions for use (i.e., this user manual)
	Follow the instructions for use (i.e., this user manual), may be combined with website
	Warning sign: warnings apply
	Special waste disposal regulations apply (EU)
	Safety according to class II electrical equipment (IEC 60601-1) *(applicable to eego amplifier)*
	Protective earth (ground)
	Applied parts: type BF (IEC 60601-1)
	Applied parts: type CF (IEC 60601-1) *(only applicable if on device label)*
	MR Unsafe (ASTM F2503-13)
IP20	IP Code (International/Ingress Protection Rating) as defined in international standard IEC 60529. (IP20: protection against fingers or objects < 12mm, not protected from liquids)
	Medical Device
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

	QR code for the UDI encoding (human readable text is next to this) (UDI: Unique Device Identification)
Symbols for Outer Packaging (for transportation)	
	Humidity range symbol
	Temperature range
	This side up
	Handle with care
	Not getting wet

APPENDIX E: NËO MONITOR DATASHEET

Product Name: **n**ëo **monitor system / n**ëo **monitor** software

Product Code REF: ES-820 (system) / LE-800 (software)

Product Version: 1.5

Manufacturer:

eemagine Medical Imaging Solutions
Gubener Str. 47
10243 Berlin
Germany

Phone +49 (0)30 2904 8404
Fax +49 (0)30 2904 8405
E-Mail info@eemagine.com
Web www.eemagine.com

Example system label:

Example software label:

OQC passed

for part(s) with SERIAL / LOT number as indicated on product / package

Classification: CE class IIa
Protecting class I (ME equipment)

Compatibility: **XC-810.50/XC-820.68** EEG touch proof adapter
XC-425 Adapter for EE-511 amplifier to 8ch amplifier accessories
XC-820/XC-830 Medical Cart (Vesa compatible)
XC-821.R Medical Monitor arm for wall norm rails (Vesa compatible)
XC-821.P Medical Monitor arm for poles (Vesa compatible)
XC-822 Medical Table Stand (Vesa compatible)

Description: **n**ëo **monitor** is used for electroencephalography (EEG) acquisition and review EEG and aEEG signals for monitoring the brain status of neonatal patients. The software and system on which it is installed is to be used in a hospital environment by qualified clinical practitioners. It provides neurophysiological data to healthcare professionals to support neurological screening, monitoring and diagnostic workflows.

LE-800 is the catalogue number for the **n**ëo **monitor** software.
ES-820 is the catalogue number for the **n**ëo **monitor system**, which may be extended with a country code (for the power/cable supply):
As example:

- # ES-820.EU = Europe
- # ES-820.UK = United Kingdoms
- # ES-820.US = United States of America

nëo monitor system is compatible with selected accessories and can be connected to mount options with VESA interface.

Specifications:

Touch Screen Monitor	
Weight	4.5 kg
Screen size	15”, 16:9 Ratio
Dimensions	385 x 290 x 45 mm
Resolution	1920 x 1080 Pixel Full-HD
Mount	Integrated VESA-100 interface
Electrical Safety Classification	Class I
Data Acquisition	Specifics for **n**ëo monitor system below, for more details, see: *eego amplifier EE-41x EE-43x User Manual*, or *eego amplifier EE-5xx User Manual*
Bipolar channels	6
Referential channels	Max. 8
Sampling Rate	512 Hz
Resolution	24 bit
Input impedance	>1 GΩ
Shielding	Actively shielded inputs
Amplifier size	86 x 100 x 16 mm (EE-411) / 115 x 90 x 20 mm (EE-511)
Input signal range	150 – 1000 mV_{pp}
Electrical Safety Classification	Class II, type BF applied parts

Software	
Operation System	Windows 10/11 (64bit)
Monitoring features	Real-time EEG aEEG (computed) Continuous Burst-Suppression-Ratio (BSR) Continuous Inter-Burst-Interval (IBI) Impedance Measurement Event-Markers Online-Review mode
Hardware	
Processor	Intel Core™ i5 / Intel Core™ i7
Working Memory	8 GB
Connectivity	2x USB 3.0
Storage	mSATA 480GB SSD
Graphics	Intel® HD Graphics GT-Series
Operation environment	
Temperature	15°C to 35°C
Relative humidity	15% to 60%, non-condensing
Atmospheric pressure	86 to 106 kPa
Storage Conditions	
Temperature	10°C to 40°C
Relative humidity	5% to 70%
Atmospheric pressure	86 to 106 kPa
Power Supply	
Power supply Unit	Integrated power supply
Power supply voltage	100-240V / 50 / 60 Hz
Power consumption	max. 110 W

Connection to compatible products:
See compatibility list above.

Warning:
Proper use of the **ES-820 n**ëo monitor system and **LE-800 n**ëo monitor software depends on carefully reading of all instructions including the descriptions and labels that come with or on the devices. Inaccurate measurements may be caused by incorrect use of the device. Non-compliance with warnings and safety regulations may result in severe personal injury and total loss of equipment.

APPENDIX F: EU Declaration of Conformity

Hereby we declare in exclusive responsibility that below identified product fully complies with the regulations of the Medical Device Regulation (EU) 2017/745 (MDR) on medical devices .

nëo monitor

EEG/aEEG monitoring

Product version 1.5

The product is classified according to the MDR Annex VIII, rule 11, as **CE class IIa** device, and meets the *General Safety and Performance Requirements* of the MDR Annex I.

Following MDR Article 52 we apply the conformity assessment procedure in accordance with MDR Annex IX (Chapters I and III), and issue this declaration of conformity as manufacturer.

The product is marked with CE 0044

The applicable sections of the following standards have been used as a basis for the conformity:

- <ISO 14971:2019>
- <IEC 60601-1:2005/A1:2012>
- <IEC 60601-1-2:2014>
- <IEC 80601-2-26:2019>
- <IEC 62366-1:2015>
- <IEC 62304:2006>
- <ISO 15223:2021>
- <ISO 20417:2021>

This declaration COC-QM-0003 is valid for product codes REF as stated in the appended product list.

The corresponding *Global Medical Device Nomenclature* (GMDN) code is: 38736.

We are registered with HIBCC, with *Labeler Identification Code* (LIC): B195.

EUDAMED assigned our *Single Registration Number* (SRN): DE-MF-000005560.

The *notified body* involved in the assessment of our quality management system is:
<notified body name, address>.
Current certificate EN ISO 13485:2016 <registration information>.

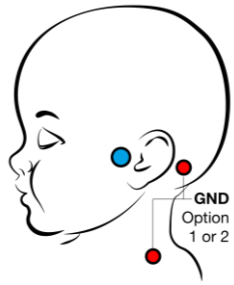
Dated at Berlin, Germany, on the _____ day of _____ <2025>.

_____

<CEO>
eemagine Medical Imaging Solutions GmbH

For the exact <information> in the above text, see the official, signed declaration COC-QM-0003. The contents of similar conformity statements may be different in countries outside the European Union.

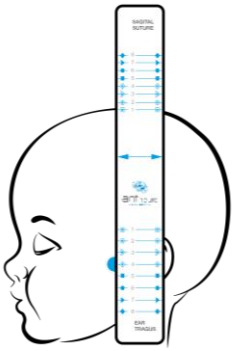
APPENDIX G: nëo aEEG ELECTRODE POSITION AID INSTRUCTIONS



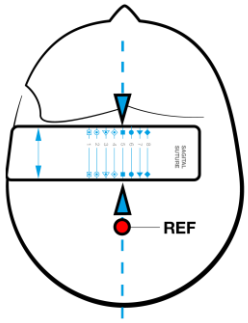
Place the ground (GND) electrode on either the shoulder or mastoid, noted as red dots.

Select either the small or large position aid.

Identify the tragus of the ear, noted as a blue dot.

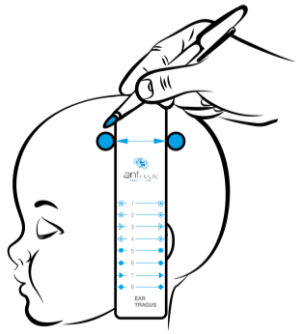


Align the position aid next to the ear tragus.



Place the reference (REF) electrode centrally posterior to the large fontanelle, noted as a red dot.

Gently slide the position aid up and down until the symbol at the ear tragus matches the symbol at the sagittal suture line.



Mark, for example with a surgical marker, at both the anterior and posterior sides of the horizontal arrows of the position aid, noted as blue dots.

The anterior position is the central electrode, and the posterior position is the parietal electrode. In the example image, C3 and P3 are marked.

Repeat for the other side of the head.

APPENDIX H: Hardware Environment for nëo viewlite software

Components to be used in combination with **n**ëo viewlite software must meet the requirements listed in Table below. The setup as a whole must meet local medical safety regulations.

Compatible items	Requirements
Operating System	• Windows 10 / 11 Professional 64 bit English
Processor	• Intel Core Quad CPU 3GHz or better
RAM	• 3 GB or more
Graphic Card	• ATI Radeon R300 9800 or later, Nvidia GeForce FX Series or later